s5i IMAGING SYSTEM

VOLCANO™

s5i Imaging System Intravascular Ultrasound

Service Manual

CE 0086 Complies with the Council Directive 93/42/EEC

c UL us Product meets UL's safety requirements

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Chapter 1 Introduction

This chapter contains information on product support, warranty, and patents and trademarks.

Product Support

Read and Review Manual before Operation

Carefully read and review the entire Volcano s5i Service Manual before attempting to service the system.

Technical Support

For additional s5i Imaging System product support, contact the Volcano Technical Support by telephone or email:

Volcano Field Service / Technical Support Centers

USA
Volcano Corporation
2870 Kilgore Road
Rancho Cordova, CA 95670
United States of America
(800) 228-4728 Option (5) or Ext. 7021
(916) 281-2669 FAX
technicalsupport@volcanocorp.com

Europe
Volcano Corporation Europe SA/NV
Excelsiorlaan 41, Keiberg
Zaventem-Diegem
B-1930 Belgium

Warranty

NOTICE: Manufacturer's Specifications and Policies Subject to Change. Volcano Corporation reserves the right to make changes in the products described in this manual in order to improve design or performance. Reproduction or distribution of any portion of this manual without the prior written consent of Volcano Corporation is prohibited.

LIMITED WARRANTY

Subject to the conditions and limitations on liability stated herein, Volcano Corporation ("VOLCANO") warrants that the Volcano s5 (the "System") as so delivered, shall materially conform to Volcano's then current specifications for the System, for a period of one year from the date of delivery. ANY LIABILITY OF VOLCANO WITH RESPECT TO THE SYSTEM OR THE PERFORMANCE THEREOF UNDER ANY WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER THEORY WILL BE LIMITED EXCLUSIVELY TO SYSTEM REPAIR, REPLACEMENT OR, IF REPLACEMENT IS INADEQUATE AS A REMEDY OR, IN THE OPINION OF VOLCANO, IMPRACTICAL, TO REFUND OF THE PRICE PAID FOR THE SYSTEM. EXCEPT FOR THE FOREGOING, THE SYSTEM IS PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF FITNESS, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT. FURTHER, VOLCANO DOES NOT WARRANT, GUARANTEE, OR MAKE ANY REPRESENTATIONS REGARDING THE USE, OR THE RESULTS OF THE USE, OF THE SYSTEM OR WRITTEN MATERIALS IN TERMS OF CORRECTNESS, ACCURACY, RELIABILITY, OR OTHERWISE. Buyer understands that VOLCANO is not responsible for and will have no liability for any items or any services provided by any persons other than VOLCANO. VOLCANO shall have no liability for delays or failures beyond its reasonable control.

Additionally, this warranty does not apply if:

1. The System is operated in other than a manner prescribed by Volcano Corporation in the Operator's Manual, and/or supplements.
2. The System is operated in a manner that is not in conformance with purchase specifications and specifications contained in the Operator's Manual, and/or supplements.
3. The System is not maintained in accordance with procedures in the Operator's Manual, and/or supplements.
4. The System is repaired, altered, or modified in any way by other than Volcano Corporation authorized personnel, or without Volcano Corporation authorization.

Contact Volcano Corporation Field Service for instructions and issuance of a Return Material Authorization if claims under this warranty become necessary and if the System or components of the System are to be returned. The System or components will not be accepted for warranty purposes unless the return has been authorized by Volcano Corporation.

System parts or components repaired or replaced under warranty bear the same warranty expiration date as the original equipment. Consumable parts (data disks, batteries, among others) are warranted only against defects in materials and workmanship. System parts purchased outside the original warranty period are warranted for a period of 90 days, subject to all of the

restrictions contained in this Limited Warranty. Use of unauthorized replacement parts may void the warranty. In all cases, Volcano Corporation will be the sole judge as to what constitutes warrantable damage.

Patents and Trademarks

Patents

This product, and the use thereof, may be covered by one or more of the following U.S. and international patents: 4917097, 5081993, 5183048, 5257629, 5368037, 5453575, 5590659, 5601082, 5603327, 5779644, 5857974, 5921931, 5935072, 5938615, 5993393, 6036650, 6049958, 6080109, 6110314, 6123673, 6165128, 6200268, 6213950, 6238347, 6254542, 6283920, 6283921, 6381350, 6618916, 6776763, CA 1306050, CA 2112391, CA 2133475, CA 2163213, CA 2235947, CA 2308457, DE 69031685.2, DE 69213463.8, DE P3854838.0, DE P69516444.9, EP 0339087, EP 0386058, EP 0473665, EP 0596974, EP 0611291, EP 0637937, EP 0671221, EP 0707453, EP 0750883, EP 0871043, GB 2208138, GB 2212267, GB 2233094, GB 2246632, GB 2287375, GB 2301892, GB 2315020, JP 2020066, JP 2905489, JP 3188470, JP 3194582, JP 3344422, AU776527, 6899682.

Other U.S. and international patents pending.

Trademarks

The following are trademarks of Volcano Corporation:

AVANAR®

Eagle Eye™ *Gold*

VOLCANO™

ChromaFlo®

Visions®

How To Use This Manual

The purpose of this service manual is to provide the information necessary to install and service the Volcano Corporation s5i and s5i/GE Intravascular ultrasound (IVUS) Imaging System. For clarity the generic term s5i is used to describe common s5i and s5i/GE features. Unique features to the s5i/GE product are called out within the appropriate sections of the manual. This service document is composed of 10 chapters, system block diagrams, and field service technical bulletins.

Chapter 1 Introduction

This chapter contains information on product support, warranties, patents and trademarks, and a description of how to use this manual.

Chapter 2 Description of the Product

This chapter contains a description of the products intended use, an overview of the system and detailed description of each major component.

Chapter 3 Theory of Operation

This chapter contains the s5i theory of operation including hardware and software boundaries and environments.

Chapter 4 Pre-Installation

This chapter contains pre-installation requirements for the s5i system.

Chapter 5 Installation

This chapter contains instructions for site installation of the s5i system.

Chapter 6 Software Installation

This chapter contains instructions for loading the s51 system software.

Chapter 7 Functional Checks

This chapter contains the required steps to verify the proper operation of the system after installation or when completing a preventive or corrective maintenance action. These performance checks are also useful for identifying and isolating system failures.

Chapter 8 Preventive Maintenance

This chapter contains the preventive maintenance procedure for the s5i system.

Chapter 9 Troubleshooting

This chapter contains procedures to be used by field service representatives to identify and isolate system problems.

Chapter 10 Repair

This chapter contains Removal and Replacement procedures for the s5i Imaging system components and a description of the built in test routines for use by field service engineers.

Backup and Restore

This section provides detailed instructions on backing up and restoring the s5i system.

Parts Breakout

This chapter contains exploded view drawing of the s5i imaging system and system components, and also includes a detailed part list.

Technical Specifications

This chapter contains the s5i Imaging System technical data.

Glossary

Field Service Bulletins

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Appendix's

Chapter 2 Description of the Product

The Volcano s5i Imaging System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures.

The Volcano VH System is intended to be used in conjunction with imaging catheters during diagnostic ultrasound imaging of the peripheral and coronary vasculature. The VH System is intended to semi-automatically visualize boundary features and perform spectral analysis of RF ultrasound signals of vascular features that the use may wish to examine more closely during routine diagnostic ultrasound imaging examinations.

ChromaFlo® is indicated for qualitative blood flow information from peripheral and coronary vasculature; flow information can be an adjunct to other methods of estimating blood flow and blood perfusion.

The device comprises a complete diagnostic imaging system when connected to a sterile single use intravascular ultrasound imaging catheter. The device has been designed to optimize the performance, safety and efficacy of the system when used with any of the family of Volcano synthetic aperture IVUS catheters. The IVUS catheters are inserted into the coronary arteries and vessels of the peripheral vasculature under angiographic guidance. As such, the system is required to be operated within an operational angiography imaging environment.

The system has a distributed architecture. The system is intended to be integrated into existing and newly installed catheter laboratories (angiography suites.) The system configuration is flexible in order to fit into the existing catheter laboratory work flow and environment. To meet these design inputs the system utilizes mutually compatible (industry standard) input/output interfaces wherever possible. The s5i is intended to interface to the following input/output devices within the patient environment:

- Custom Volcano supplied bedside mounted Joystick,
- Custom Volcano supplied bedside mounted Control Station,
- Existing industry standard EKG system – patient isolated EKG output, and
- Existing exam room monitor, Volcano supplied bedside rail mounted monitor, or Volcano supplied ceiling mounted exam room monitor.

The s5i system is a medical device designed to insure safety and mutual compatibility with existing and newly installed angiography suites. The s5i system incorporates an AC safety isolation transformer to limit leakage currents. The s5i system connects to the IVUS catheters via a Patient Interface Module (PIM) which contains a type CF (intended for direct cardiac application) defibrillator proof isolation boundary. All other input/output interfaces within the patient environment utilize both primary and secondary protective earth connections to limit enclosure leakage currents. The primary protective earth connection for the s5i joystick and control station is through the bedside rail mount. The secondary connection is via a safety ground wire directly to the bedside protective earth system. The s5i monitor and EKG interfaces utilize the existing protective earth connections of the monitor and EKG system and a secondary protective earth connection from the bedside protective earth bus to the s5i main chassis potential equalization post.

The s5i video output is intended to be displayed in the exam room preferable on an existing industry standard SXGA (1280x1024) exam room monitor. If the monitor does not have a native pixel resolution of 1280x1024, then the monitor must support aspect ratio correction to maintain mutual compatibility with the s5i system. Aspect ratio correction is a standard feature on today's state of the art high end video monitors.

To mitigate the risk of reciprocal interference, the s5i is compliant with IEC 60601-1-2 class A emission levels, although much higher level emission is permissible under the diagnostic ultrasound standard IEC 60601-2-37.

s5i Central Processing Unit (CPU)

The CPU is a high performance dual Xeon based system. The operating system is Windows XP professional. The Volcano s5i application software is designed to perform real time intravascular ultrasound imaging while simultaneously running the VHIVUS tissue classification algorithm. The application software contains a DICOM3 compliant interface, a work list client interface, and proprietary Innova interfaces for connection to GE Innova angiographic systems.

The CPU can be located in a number of locations, such as in the control room, the patient exam room or in an equipment room. The location is driven by the site installation requirements and end user preferences up to a maximum cable distance of 30 meters (98.4 feet) from the patient table.

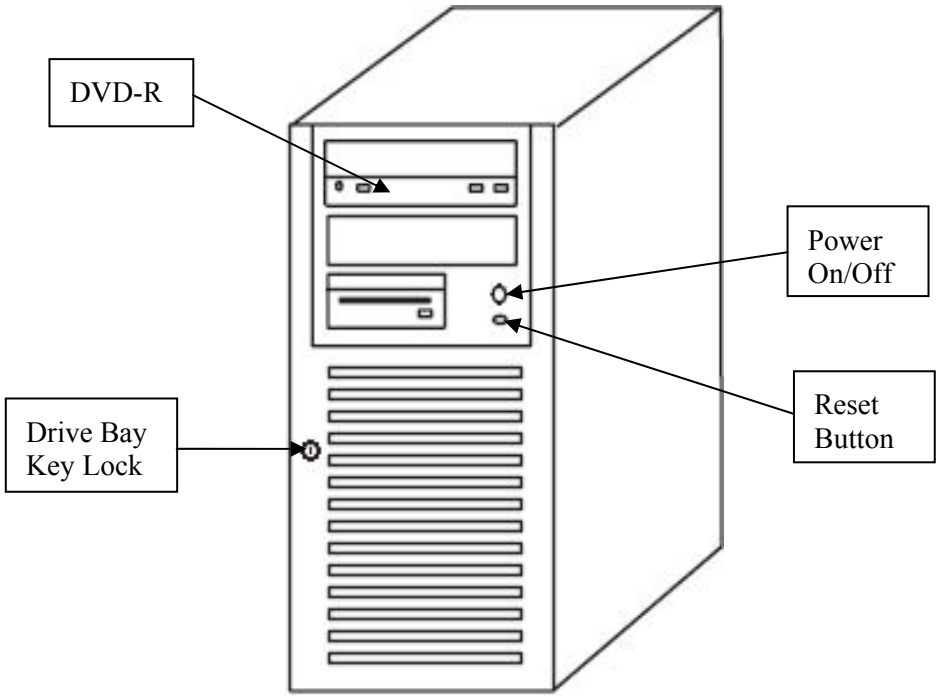


Figure 1 s51 Central Processing Unit Front View

The CPU can be controlled any combination of the following: a custom control station, a second control station, a joystick controller, a PS2 keyboard with touchpad. The CPU

has four USB interfaces for connecting peripheral equipment. Available USB devices for connection to the CPU include the custom control stations, the joystick, and a color printer. For remote (up to 30 meters) connections to the CPU off-the-shelf USB 1.1 extenders are utilized. The USB interfaces on the CPU support the USB 2.0 high speed interface. The USB 1.1 performance is adequate for all man machine and printer interfaces. A USB2.0 high speed interface is needed to support remote archiving tasks. The CPU has a standard 10/100/1000 baseT Ethernet network interface for connection to local area networks. For more specifications, see CPU Hardware on page 166

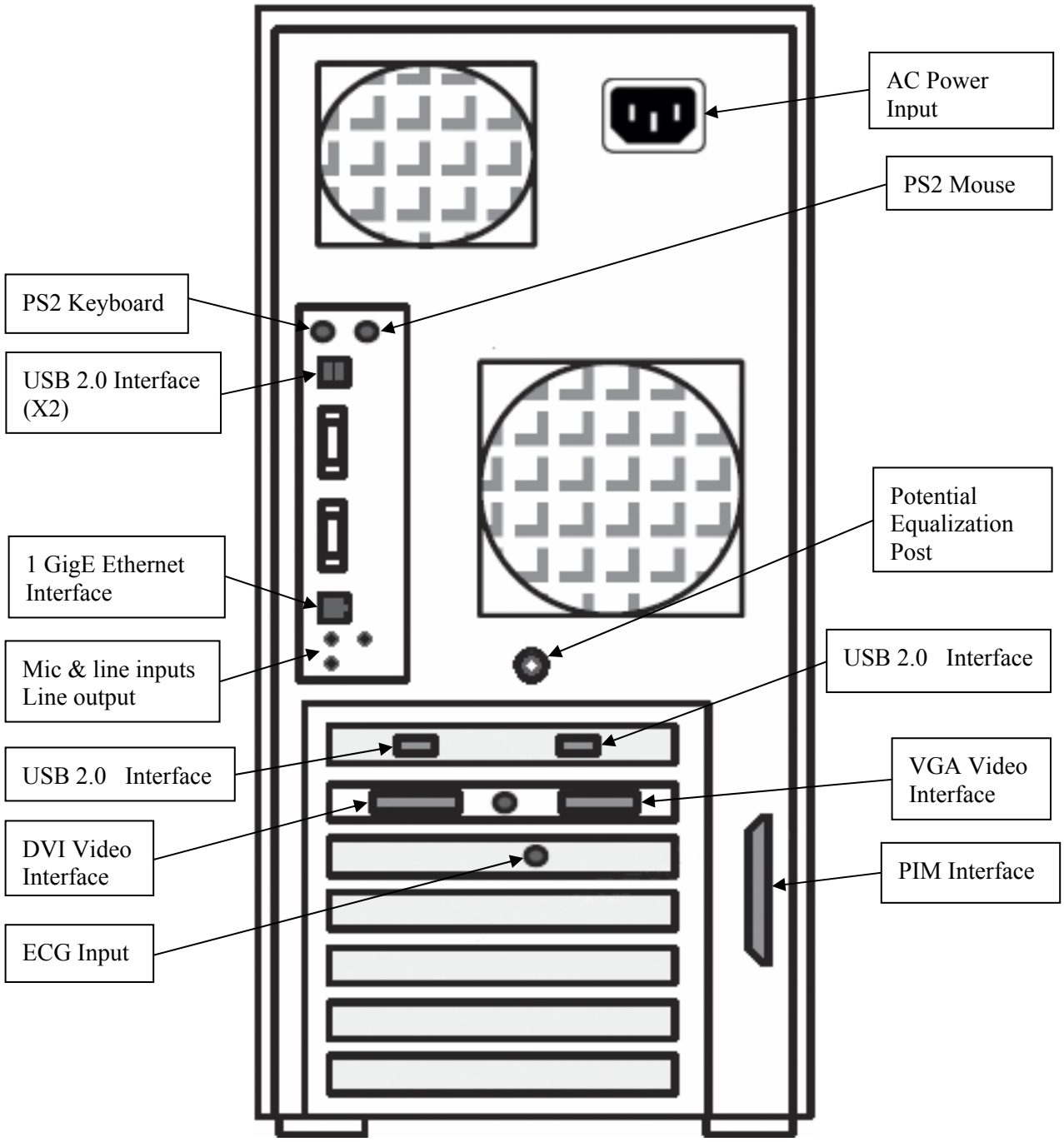


Figure 2 CPU Rear View

Isolation Transformer

The isolation transformer is a medical grade transformer compliant with IEC 60601-1. The transformer has a 4KV dielectric withstand and limits the earth leakage current to less than 100 micro amps in normal condition and less than 500 micro amps in single fault condition. For more specifications, see Isolation Transformer Hardware on page 167.

Figure 3 Isolation Transformer Front view

Isolation Transformer Mounting Options

The isolation transformer should be placed on the floor next to the CPU.

Isolation Transformer Interface

The isolation transformer has 6 IEC C14 isolated AC power outlets and one IEC 320 C13 AC power input. The transformer has a power switch that should be turned off when servicing the system. The transformer label shows which of the provided fuses are to be used depending on which of the power voltages 100VAC, 120VAC, and 220-240VAC is selected. All required fuses ship with the transformer and the correct fuse must be selected and installed during the system installation. All AC power powered s5i equipment connected to the CPU should be powered from the isolation transformer.

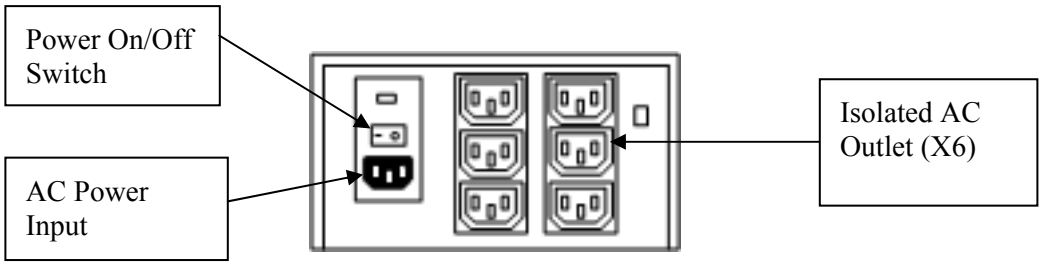


Figure 4 Isolation Transformer Front view

s5i Control Station

The Control Station contains a simple to use custom IVUS interface with frequently operated functions mapped to contact closure switches. The dome switches are covered with a membrane overlay and they provide a tactile feedback to the operator upon closure. A trackball is provided to navigate a pointer on the graphical user interface of the system. A slide out keyboard is located on the bottom for manual text entry. For more specifications, see Control Station Hardware on page 167.

Figure 5 Control Station

Control Station Mounting Options

The control station is designed to support a variety of different installations options. The station can be placed directly on a desktop surface. With the optional bedside mounting kit, the Control Station can be affixed directly to the bedside rail. This mounting kit is slipped over the rail and fixed in place by tightening two hand screws. There is a standard four hole VESA mount on the underside to allow other mounting configurations.

Control Station Interface

The control station is powered from and communicates with the CPU using a standard USB 1.1 interface. The unit comes with an approximately 3 meter USB cable. For operations at distances between 3 meters and 30 meters from the CPU, the USB 1.1 interface can be extended using off-the-shelf USB 1.1 extenders. When the Station is located within the patient environment (within 1.5 meters of the patient table) then the protective earth ground post (located on the center rear of the device) must be connected to the exam room protective earth system using the provided green/yellow safety cable to insure patient safety.

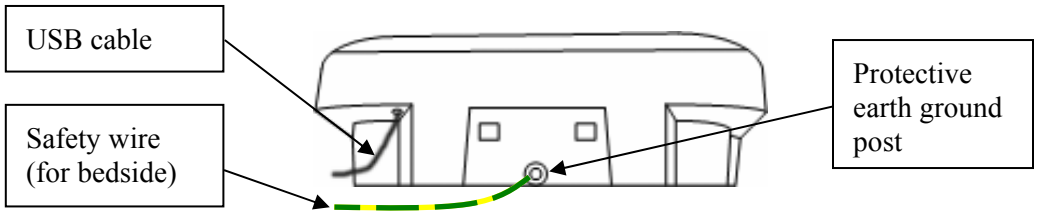


Figure 6 Control Station Rear View

s5i Series Control Panel

The s5i system is managed through the control panel, which is a part of the Control Station. . The system allows multiple control panels to be mounted in both the exam room and/or the control room. The components of the control panel are shown below and include:

- Trackball: used to position the cursor on the screen
- Screen selection keys: the keys labeled Settings, Record, Home, Save Frame, etc.
- Select (+) and Menu (-) keys
- Bookmark key
- Standard alphanumeric keyboard (retracts below control panel)
- ChromaFlo® key
- Keyboard indicator

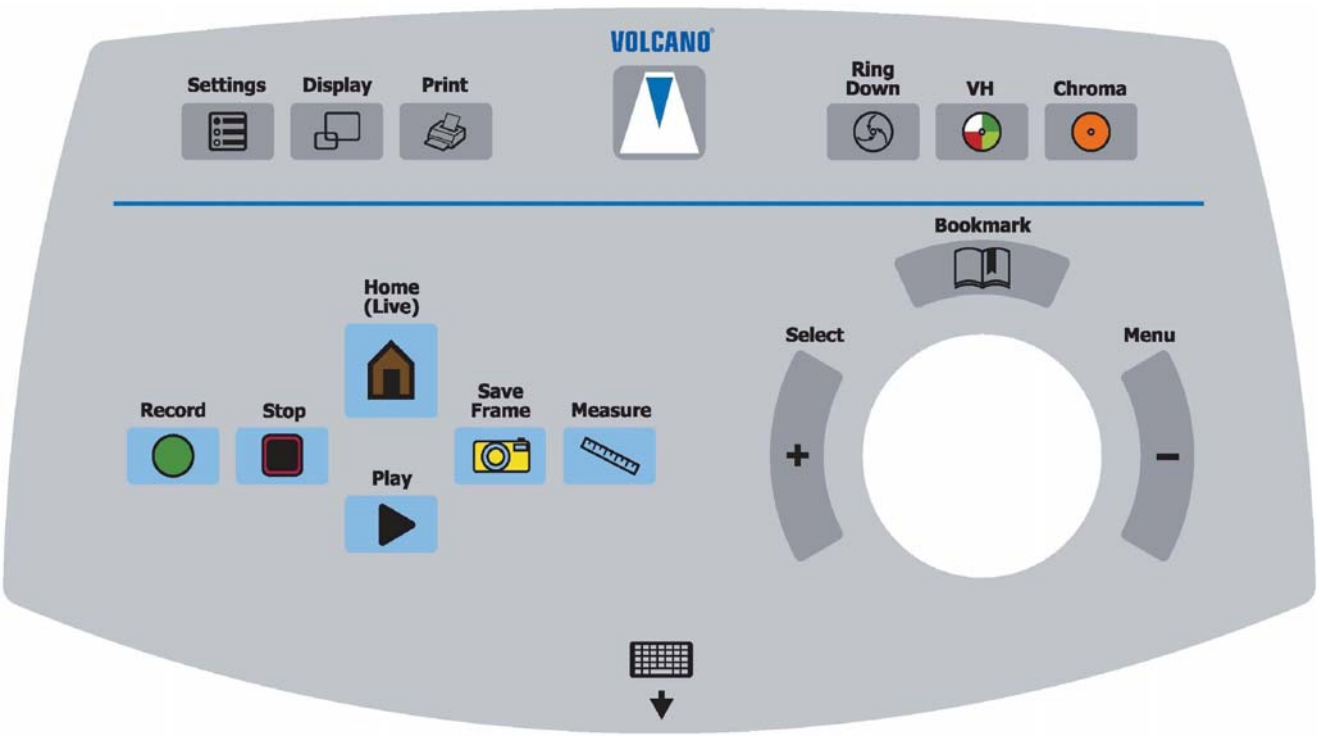


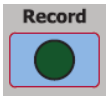
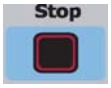
Figure 7 Control Panel (Part of Control Station)

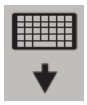
Trackball

The trackball moves the cursor on the monitor to allow function selection, location annotation and measurement.

Screen Selection Keys

There are several screen selection keys on the Control Panel.

Control Panel Key	Description
	Illuminates when the system is plugged in.
	Settings: Change system settings like date and time; also permits setting and editing default configurations.
	Display: Provides enlarged view for printing.
	Print: Prints a 6 x 4 inch photo of the current image on the screen.
	Ring Down: Turn Ring Down on or off.
	Chroma: Turns ChromaFlo on or off
	VH: Turns VH on or off
	**Record:** Records a video loop
	**Stop:** Stops the recording of a video loop. Press to pause during the play mode.
	Home: Press to view the live image.
	Play: Play a recorded video loop.
	Save Frame: Press during Live mode to save one frame.

Control Panel Key	Description
	Measure Menu: Provides access to measurement options such as diameter, length, and borders.
	Bookmark: Press while recording a loop to select specific areas of interest.
	Select (+) key: Press to select tabs, areas, or points. It is similar to left-clicking with a mouse.
	Menu (-) key: Press to end your selection points. It is similar to right-clicking with a mouse.
	**Keyboard**: Points to the retractable keyboard beneath the control panel

Alphanumeric Keyboard

A standard alphanumeric keyboard is contained in a retracting tray under the control panel and is used for data entry and image annotation. To use the keyboard, pull the latch underneath the keyboard tray and pull the keyboard tray out. Push the keyboard tray back in when you are finished using it.

Joystick

The Joystick is a sealed off-the-shelf USB pointing device used to move the cursor on the graphical user interface from the bedside. For more specifications, see Joystick Hardware on page 168.

Figure 8 Joystick

Joystick Mounting Options

The Joystick has a standard bedside rail mounting clamp. The unit is slipped over the rail and fastened in place by tightening a single hand screw.

Joystick Interface

The joystick is powered from and communicates with the CPU using a standard USB 1.1 interface. The unit comes with a ~3 meter USB cable. For operations at distances between 3 meters and 30 meters from the CPU, the USB 1.1 interface is extended using off-the-shelf USB 1.1 extenders. The Joystick is located within the patient environment (on the bedside rail) the protective earth green/yellow ground wire must be connected to the exam room protective earth system in order to insure patient safety.

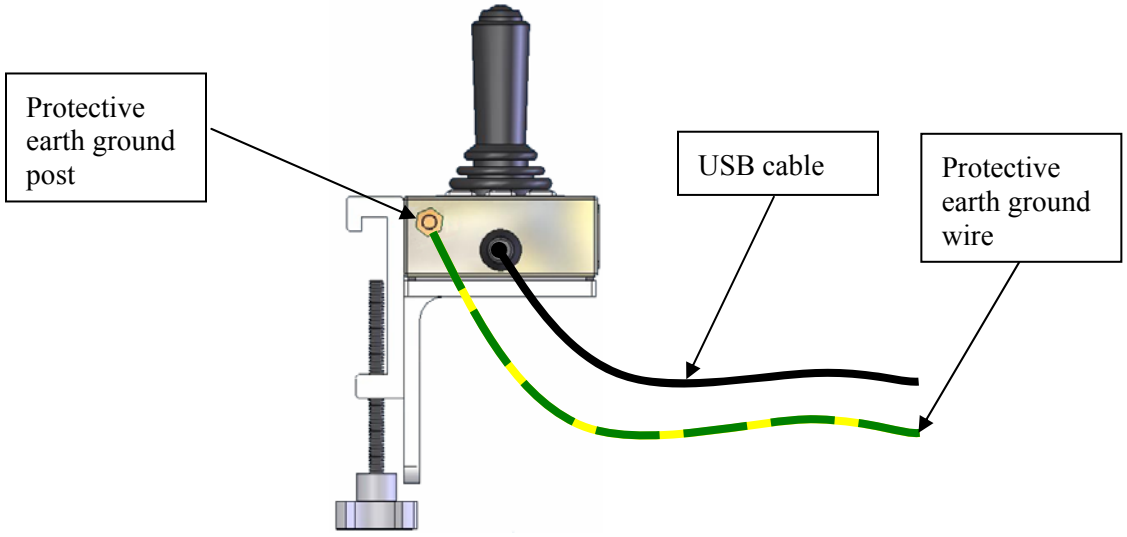


Figure 9 Joystick Side View

Control Room Monitor

The control room Monitor is an off-the-shelf 19" flat panel monitor. The monitor has a native pixel resolution of 1280x1024. The monitor accepts DVI-D, DVI-I and VGA video inputs. The monitor is AC powered unit and is compliant with IEC 60950. For more information see Control Room Monitor Hardware on page 168.

Figure 10 Control Room Monitor

Control Room Monitor Mounting Options

The control room monitor comes with a monitor stand for desktop use. The monitor can be removed from the stand and mounted to an optional wall mount kit using the four Vesa threaded screw holes on the back of the monitor.

Control Room Monitor Interface

The control room monitor is connected to the s5i CPU using the DVI-D interface. The 3 meter DVI-M to DVI-M cable provided with the installation kit MUST be used. The DVI cable provided by the manufacturer MUST NOT be used and should be discarded. The control room monitor is connected to isolated AC power from the isolation transformer using the 3 meter IEC C13 to C14 cable provided. The AC power cord provided by the manufacturer must NOT be used and should be discarded.

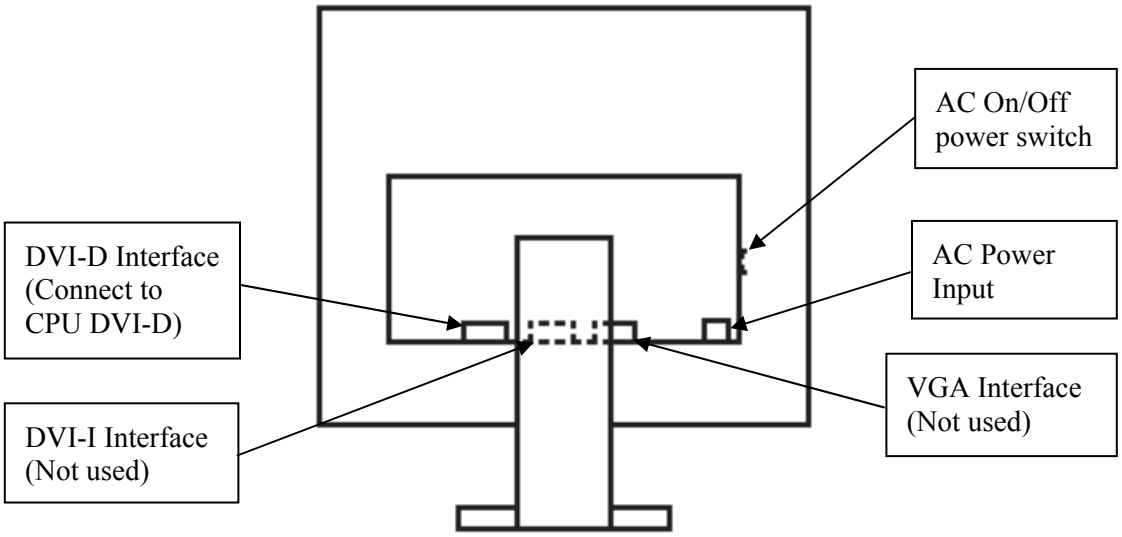


Figure 11 Control Room Monitor Rear View

Exam Room Monitor

The s5i system software revisions 2.2 and above provides analog SXGA 1280x1024 60Hz video on the VGA connector of the CPU. The SXGA video standard appears to be the most common computer video currently in use in the coronary catheter laboratory. The s5i integration process requires either access to or the addition of an exam room monitor capable of displaying the SXGA s5i video. Coronary catheter laboratories having at least four monitors (two being color capable) available in the exam room are generally considered good candidates for s5i integration. If the laboratory does not contain at least four monitors (two being color) then the hospital must adopt one of a variety of solutions offered by Volcano and our integration partners to add a fourth color monitor to the exam room. The addition of a color monitor to the exam room is outside the scope of this service manual.

4 way VGA Video Switch

When an existing exam room color monitor is to be shared with the s5i video and there are not any available video inputs, a four way VGA video switch option kit is available. The 4-way VGA video switch is an AC powered unit and is compliant with IEC 60950. For more specifications, see 4-way VGA Video Switch Hardware on page 169.

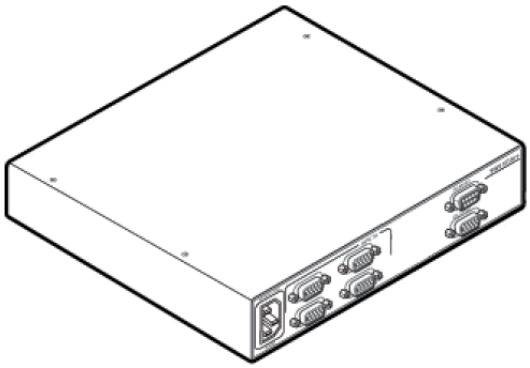


Figure 12 4-way VGA video switch rear view

4-way VGA Video Switch Mounting Options

The 4-way VGA video switch is a desktop unit. It should be positioned so that the operator has easy access the front panel video source selection switches. The manufacturer provides optional 1 RU mounting options and a remote control unit

4-way VGA Video Switch Interface

The 4-way VGA video switch is an analog video switch suitable for switching SXGA analog computer video. The switch has four VGA (15 pin high density D) video inputs and one video output. An RS232 remote control connects to a 9 pin D connector. The 4-way VGA video switch MUST BE connected to isolated AC power from the isolation transformer using the 3 meter IEC C13 to C14 cable provided. The AC power cord provided by the manufacturer MUST NOT be used and should be discarded.

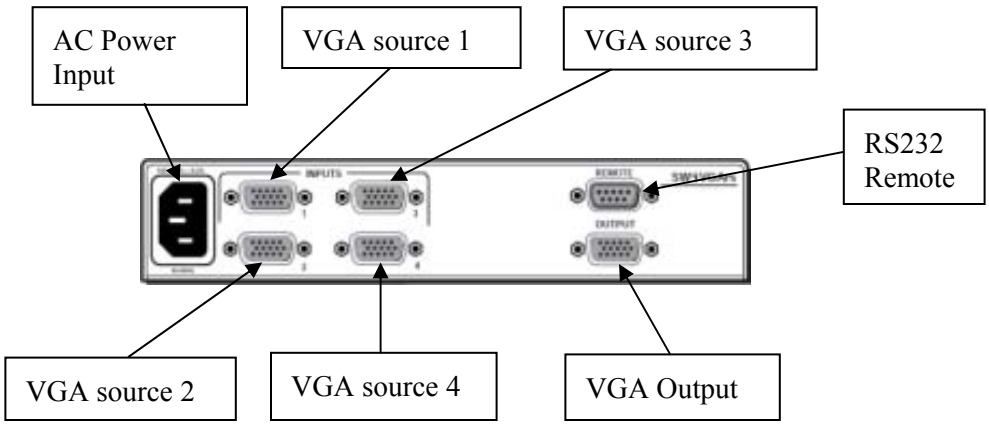


Figure 13 4-way VGA video switch rear view

Patient Interface Module (PIM)

The Patient Interface Module (PIM) interfaces Volcano IVUS catheter to the s5i system. The PIM is a type CF defibrillator proof applied part that must be on the patient table. The PIM is powered from the s5i system. For more specifications, see PIM Hardware on page 170.

Figure 14 Patient Interface Module Front View

PIM Mounting Options

The PIM has a magnetic backing that allows it to adhere to ferrous metal surfaces (such as patient table pedestals) when not in use. When in use the PIM is inserted into a bedside rail mounted PIM holder. The PIM holder is designed to be easily slid along the bedside rail.

PIM Interface

The PIM interfaces to the s5i system via a proprietary interface. The PIM to s5i cable is available in two lengths 5 and 30 meters. The s5i system must be correctly configured for the connected PIM cable length. Failure to correctly configure the PIM cable length will result in inaccurate IVUS images and incorrect measurements.

Printer

The Printer is a culmination dye transfer color printer which provides high resolution photo quality still shots of the s5i graphical user interface. The Printer is an AC powered unit and is compliant with IEC 60950. For more specifications, see Printer Hardware on page 170.

Figure 15 Printer front view

Printer Mounting Options

The Printer is a desktop unit.

Printer Interface

The Printer is a USB 1.1 device. The printer is powered from a medical grade power supply which has been substituted for the manufacturer's power supply. The power supply MUST BE connected to isolated AC power from the isolation transformer using the 3 meter IEC C13 to C14 cable provided. The AC power cord provided by the manufacturer MUST NOT be used and should be discarded.

USB Extender

The USB 1.1 interfaces can be extended over standard Cat5 cable up to a maximum distance of 30 meters (~100 feet). The USB extenders are USB bus powered devices (No Power Adapter Required.) The maximum bi-directional data transfer rate for the extenders is 12 Mbps (1.5MBps). The maximum available power to USB attached peripheral equipment is 5.0V at 300mA.

The USB extenders are comprised of two units:

1. USB to Cat5 Media Converter with USB pig tail
2. Cat5 to USB Media Converter

Figure 16

USB to Cat5 Media Converter

Figure 17

Cat5 to USB Media Converter

Chapter 3 – Theory of Operation

OBJECTIVE AND SCOPE OF THIS CHAPTER

The s5i system as discussed in the field service manual, is an amalgam of components that are brought together to provide the clinician with a distributed Intravascular Ultrasound (IVUS) system.

The imaging element is an ultrasound transducer located at the tip of an IVUS catheter. The imaging transducer is driven as a Synthetic Aperture imaging element. More on this operation will be discussed later.

The imaging transducer is approximately 1mm in diameter and 2.5mm in length. The transducer is composed of a piezoelectric component (Lead Zirconium Nitrate or PZT Ceramic) that is diced into an array of 64 elements. The PZT array is bonded to a kapton flexible circuit board that also contains five integrated circuits. The printed circuit assembly is rolled around a central metal tube, back filled with an acoustic backing material and bonded to the tip of the catheter.

The signals are passed to the system via seven wires that run the full length of the catheter. The wires are bonded to the transducer flex circuit at one end and the instrument Patient Interface Module (PIM) mating connector at the other. The PIM connector also contains a configuration EPROM. The EPROM contains the catheter's model and serial numbers and the calibration coefficients which are used by the system.

The PIM provides the patient electrical isolation, the beam steering, and the RF amplification. An additional safety feature of the PIM is a local microcontroller that monitors the performance of the system and is capable of resetting the PIM to a known safe state in the event of loss of communication or system failure. The PIM micro-controller communicates with the s5i workstation via a low speed RS232 serial link.

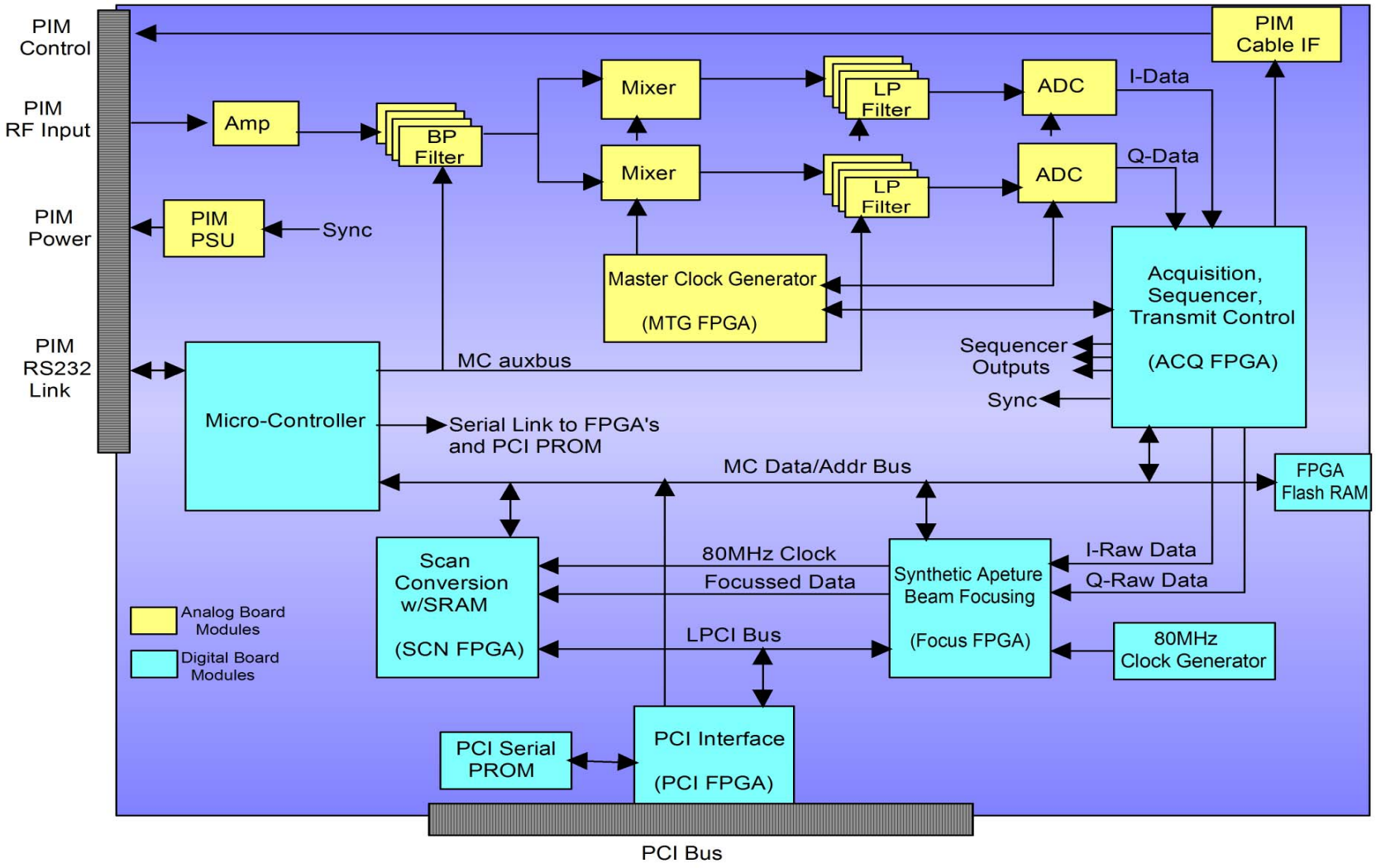
The s5i workstation is a dual Xeon workstation with proprietary IVUS signal generation and processing boards. The IVUS boards were developed as part of the Meridian project and the boards are internally called the Meridian board set. The Meridian board set comprises a Digital, an Analog and at least four filter modules and a VH printed circuit assembly (PCA.) The Meridian Analog and Digital boards are used to excite the catheter and to receive and process the gray scale IVUS signals. The VH board is used to capture and pre-process the IVUS RF signals and transfer them to the main VH processing algorithm running on the dual Xeon processors.

The PIM is directly connected to the Meridian Analog board. The Analog board provides the amplification, filtering, signal mixing, and analog to digital conversion (ADC). The analog chain base-band converts the transducer RF data to "In-Phase" and "Quadrature" (IQ) data. The ADC is 12-bits wide and converts the IQ data to a dual digital data stream.

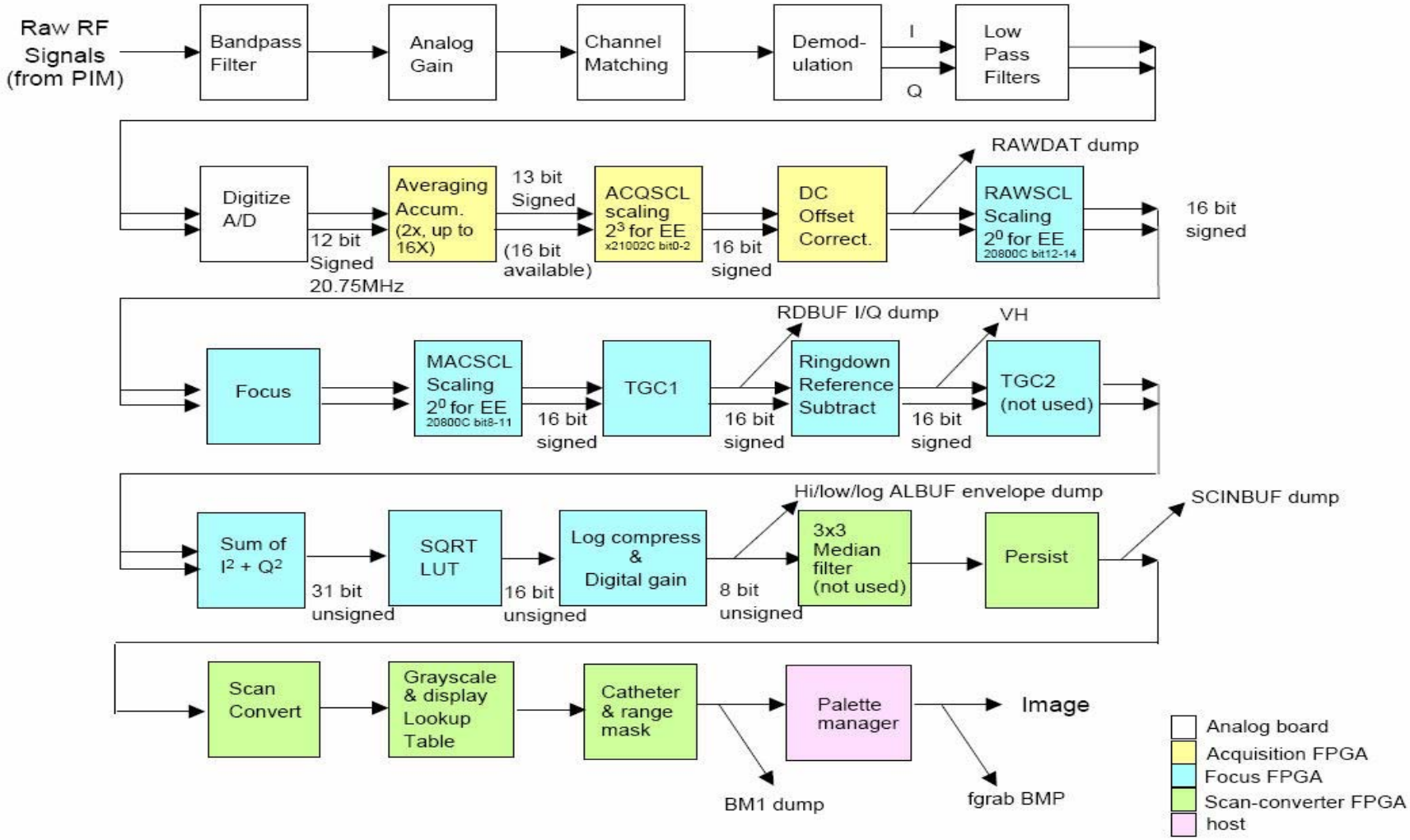
The Analog board also contains a clock generator and timing and control circuits to synchronize the system. These signals are used on both the Analog and Digital boards.

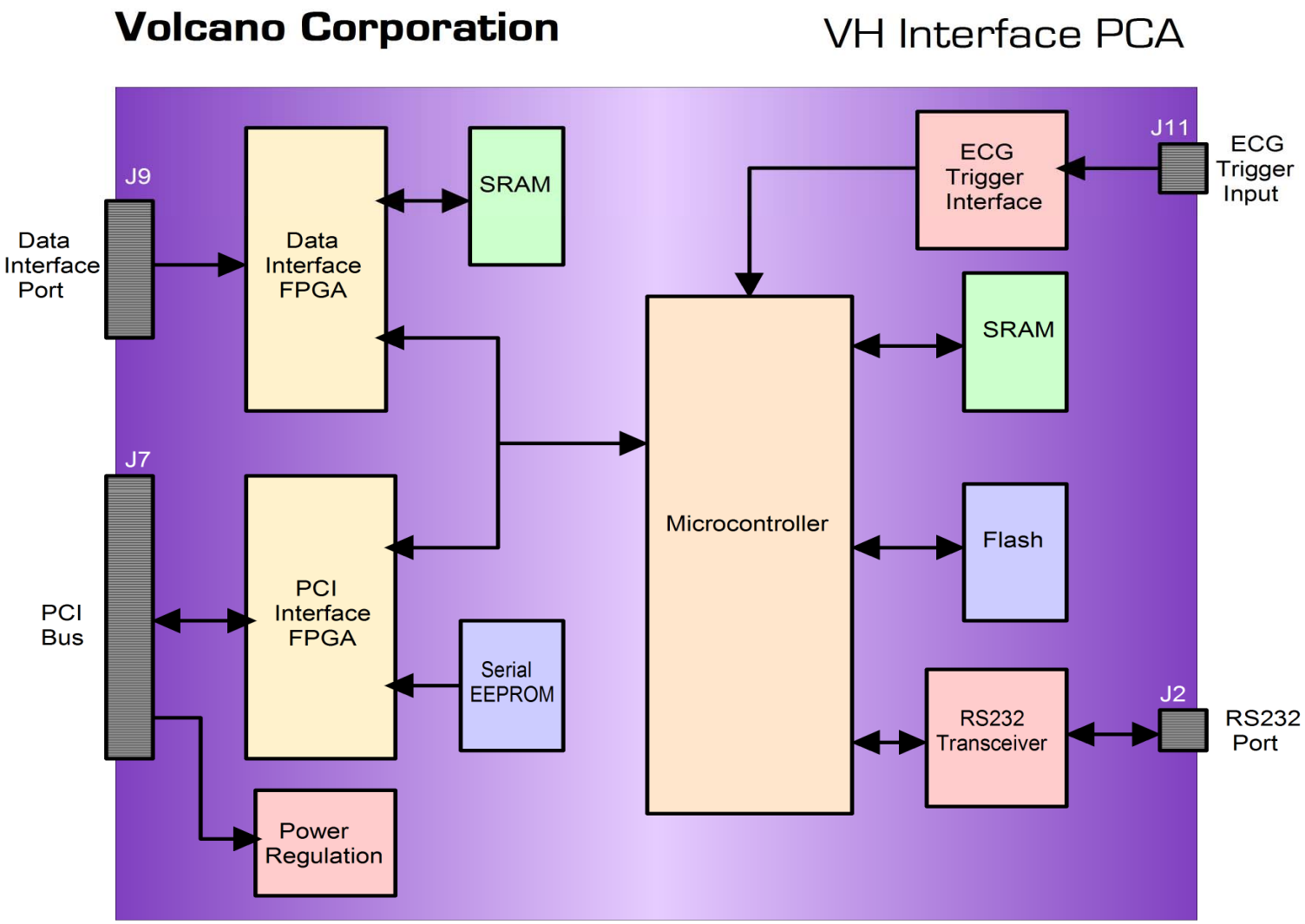
The Digital board provides the synthetic aperture signal processing and final scan conversion of the transducer vector data to Cartesian coordinates suitable for display on a standard computer graphics card. The Meridian board block diagram and Signal processing chain are depicted in the following diagram.

Meridian Imaging Boards



Meridian B-mode Signal Processing Chain




Volcano Corporation
VH Interface PCA
J9
Data Interface Port
Data Interface FPGA
SRAM
ECG Trigger Interface
J11
ECG Trigger Input
SRAM
J7
PCI Bus
PCI Interface FPGA
Serial EEPROM
Microcontroller
Flash
RS232 Transceiver
J2
RS232 Port
Power Regulation

The VH PCA, block diagram shown on the previous page, sends the base banded RF data to the host CPU. The raw RF IQ data are frame captures and are synchronized to the patient's ECG signal. The ECG trigger circuit is designed for close alignment to the R-Wave of a Lead I ECG signal. The use of alternate ECG leads may cause double triggering or shifting of the trigger point.

The absolute accuracy and repeatability of the EKG trigger is not essential for VH processing. The trigger serves two purposes:

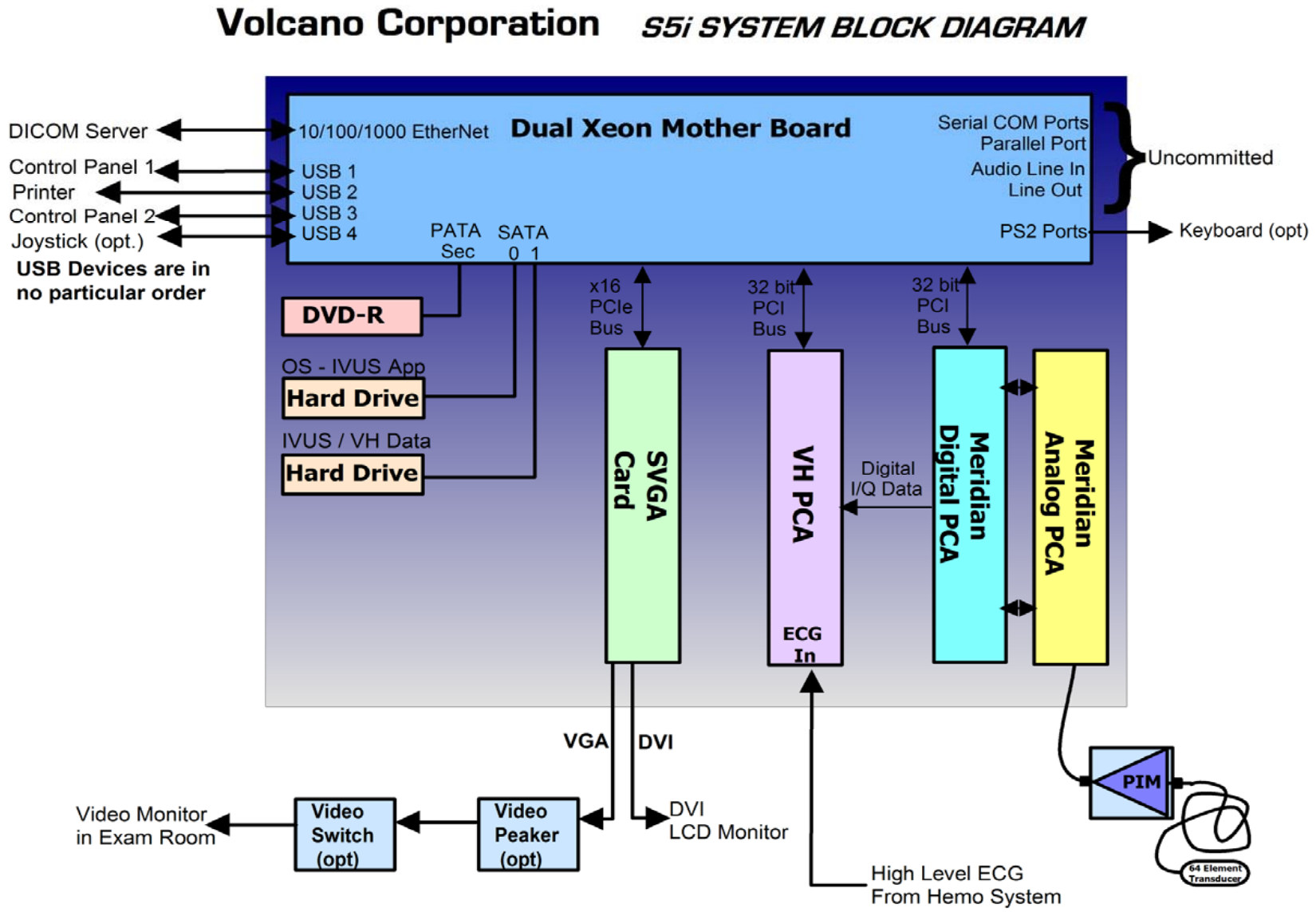
- To select individual IVUS frames for VH processing thereby reducing the number of frames requiring for VH processing.
- To reduce frame to frame movement between IVUS images slices resulting from normal cardiac motion.

The following diagram depicts the architecture of the s5i workstation. This diagram illustrates that the workstation may have several peripheral I/O devices attached to provide display, user controls and printing.

Multiple user controllers and displays can be attached thru the provided connectors and down stream signal splitters/expanders such as USB Hubs, and VGA video Splitters.

Multiple user controllers operate as parallel devices and users must cooperate to insure correct response.

Multiple display monitors are clones of the primary display monitor attached to the DVI connector of the video display adapter


Volcano Corporation
S5i SYSTEM BLOCK DIAGRAM
DICOM Server
Control Panel 1
Printer
Control Panel 2
Joystick (opt.)
USB Devices are in no particular order
10/100/1000 EtherNet
Dual Xeon Mother Board
USB 1
USB 2
USB 3
USB 4
PATA Sec
SATA 0 1
Serial COM Ports
Parallel Port
Audio Line In
Line Out
Uncommitted
PS2 Ports
Keyboard (opt)
DVD-R
OS - IVUS App
Hard Drive
IVUS / VH Data
Hard Drive
x16 PCIe Bus
32 bit PCI Bus
32 bit PCI Bus
SVGA Card
VH PCA
ECG In
Digital I/Q Data
Meridian Digital PCA
Meridian Analog PCA
VGA
DVI
Video Monitor in Exam Room
Video Switch (opt)
Video Peaker (opt)
DVI LCD Monitor
PIM
64 Element Transducer
High Level ECG From Hemo System

Chapter 4 Pre-Installation

Objective and Scope of This Chapter

This chapter defines the pre-installation requirements for the s5i and s5i/GE IVUS workstations.

It provides pre-installation data such as site preparation prior to delivery of an s5i system, product information, environmental and electrical requirements, and some additional planning aids.

This chapter also provides pre-installation data for the s5i optional equipment.

Site planning information is continually changing due to the evolution of the product.

Volcano will make every reasonable effort to maintain accuracy of site planning information.

Responsibility of Purchaser/Customer

The customer is responsible for providing an appropriate desktop location within the control room for the placement of the s5i display, control station and optional printer. The customer is responsible for locating the s5i workstation in compliance with any local or national codes and no more then 2 meters (6.5 feet) from the control room display, control station and optional printer. An available electrical wall outlet is required and must be located no more then 2.5 meters (8 feet) from the workstation.

Room Requirements

Room Climate and Altitude

The room environment where the s5i workstation and all accessories are located must be maintained (during workdays, holidays and weekends) as specified in the following table.

To ensure the user comfort while viewing images, the room temperature should be maintained between 65°F (18°C) and 75°F (24°C).

TABLE 3.1 - ENVIRONMENTAL REQUIREMENTS LIMITIATIONS

PRODUCT/ COMPONENT	HUMIDITY (1)				TEMPERATURE				ALTITUDE (4)			
	In use (2)		Storage (2)		In use (3)		Storage 93)		In use		Shipping	
	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
S5i Workstation	5%	85%	5%	85%	+15°C +60°F	+32°C +90°F	+15°C +60°F	+50°C +122°F	0m 0ft	3048m 10,000ft	0m 0ft	10668m 35,000ft
Monitor	30%	80%	10%	85%	+5°C +41°F	+35°C +95°F	-10°C +14°F	+60°C +140°F	0m 0ft	3048m 10,000ft	0m 0ft	12192m 40,000ft
Printer	30%	80%	N/A	N/A	+5°C +41°F	+35°C +95°F	N/A	N/A	N/A	N/A	N/A	N/A
Video Switch	10%	90%	10%	90%	0°C +32°F	+50°C +122°F	-40°C -40°F	+70°C +158°F	N/A	N/A	N/A	N/A
USB Extender	20%	80%	N/A	N/A	+20°C +32°F	+50°C +122°F	0°C - +32°F	+70°C +158°F	N/A	N/A	N/A	N/A

Notes:

(1) Non-condensing

(2) At 35°C (95°F) with gradient < 30% Relative Humidity/hr

(3) At 20% Relative Humidity

(4) Relative to sea level

Equipment Heat Output

Ventilation

- A well ventilated or air–conditioned work area to avoid overheating.
- A dust free work area (as much as possible).

The s5i workstation has vents on its front and back panels for ventilation. When you place the unit on a floor, make sure that objects do not block the vents on either side of the unit (see **Figure 18**).

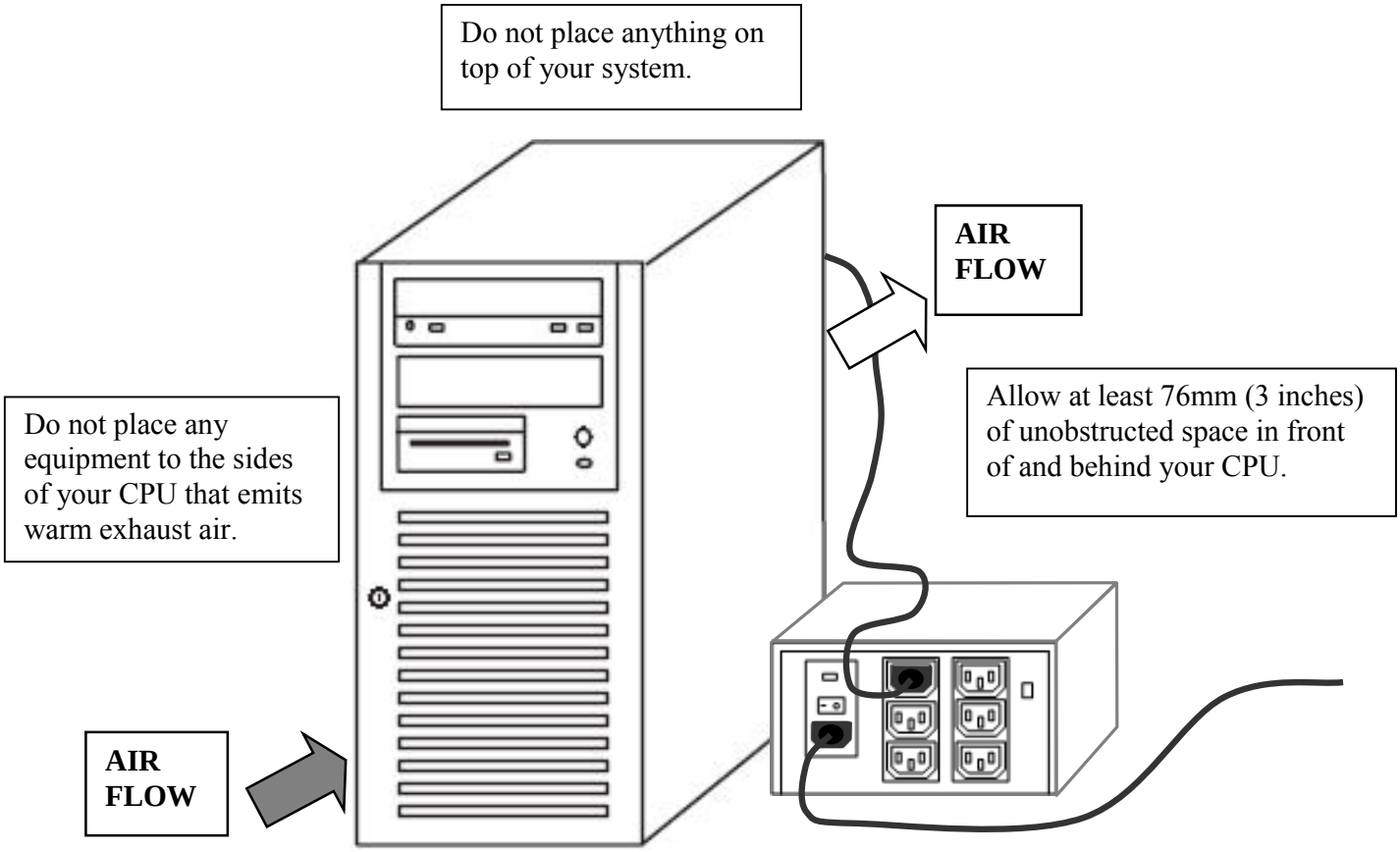

Do not place anything on top of your system.
AIR FLOW
Allow at least 76mm (3 inches) of unobstructed space in front of and behind your CPU.
Do not place any equipment to the sides of your CPU that emits warm exhaust air.
AIR FLOW

Figure 18 System Unit Vents

Power Requirements and Considerations

Systems Input:

100V, 50/60Hz
120V, 50/60Hz
220-240V, 50/60Hz
Maximum rated power 600W

Computer Workstation:

100-240V, 50/60Hz
Nominal power 250W

Monitor:

100-240V, 50/60Hz
Nominal power 65W

Printer

100-240V, 50/60Hz

Nominal power 60W

Video Switch

100-240V, 50/60Hz

Nominal power 10W

Fusing

Use Agency approved fuses only, 250V. The transformer has an internal thermal resettable fuse.

100 VAC-8AT (Bussman part number S516-8A)

120VAC-6.3AT (Littlefuse part number 0213 6.3A)

220VAC-3.15AT (Littlefuse part number 0213 3.15A)

230VAC-3.15AT (Littlefuse part number 0213 3.15A)

240VAC-3.15AT (Littlefuse part number 0213 3.15A)

Dimensions and Weights-s5i

	Height, in	Width, in	Depth, in	Weight, lb
CPU	16.5	6.75	21.25	~35
Controller	5.0	15.0	10.0	~6.6
Monitor	17.5	18.0	10.0	~35
Patient Interface Module	1.6	4.0	7.4	~4.4

	Height, cm	Width, cm	Depth, cm	Weight, kg
CPU	39.6	16.2	51	~15
Controller	12	36	24	~3
Monitor	42	43.2	24	~15
Patient Interface Module	3.8	9.6	17.75	~2

Under floor Cable Installation

The 30 meter PIM cable assembly contains a minimum of 5 discrete cables. The maximum individual cable diameter is 1 cm (0.40 in). The maximum individual cable connector required to be pushed through under floor conduit is 3 cm (1.2 in

The s5i 30 meter PIM cable assembly can be pre-ordered and pre-installed during new Angiography system installations. Alternatively, the cable can be installed at the same time as the system provided that an under floor conduit or acccessway is accessible and has sufficient space available to accommodate the s5i 30 meter cable assembly.

Under floor Cable Conduit Requirements

The recommended minimum under floor conduit diameter is 7.5 cm (3 in). This large conduit diameter is intended to insure ease of cable insertion. Smaller conduits are acceptable but may increase the time to install.

The maximum under floor cable conduit length is dependent on:

- The control room location of the under floor conduit exit point relative to the s5i workstation location.
- The exam room location of the under floor conduit exit point relative to the table base.

The minimum service loop within the exam room is 3 meter (~10 feet.) This is to insure that s5i cables do not interfere with or restrict the table movement. For ease of serviceability, the recommended control room service loop, available at the workstation, is 1 meter (~3 feet.) It is anticipated that the control room under floor conduit exit point will be up to 3 meter (~10 feet) from the desired s5i workstation location. Therefore the recommended maximum under floor cable conduit length is 23 meters (~75 feet.) If the location of the s5i workstation is more then 1 meter from the control room under floor cable conduit exit point, the under floor cable maximum length shall be reduced accordingly.

Maximum Under floor Cable Conduit Length = 23 meters (75 feet). See above rationale.

PIM Cable

When installing the under floor 30 meter PIM cable insure that the 37 pin D connector (s5i workstation end) end is routed to the intended work station location. Insure that a minimum 1 meter (3 foot) service loop is present. The bedside end should be routed through the table base or other acccessway so that the cable exits at the table base. The PIM cable exit point shall include a means (rubber grommet) to insure that the cable is protected from any sharp edges that may abrade the cable. The bedside end of the cable contains an armored jacket. The cable shall be positioned in the under floor conduit so that only the armored end of the cable is exposed. Excess cable shall be looped back into the conduit or coiled in the table base. Insure that an above floor service loop is present that accommodates the full unrestricted movement of the patient table.

ECG Cable

The under floor ECG Cable is intended for connection to an isolated bedside EKG output when an EKG output is not available at the s5i workstation location. It is preferable to connect the s5i EKG input to a local EKG output whenever available. The bedside end

should be routed through the table base or other acccessway so that the cable exits at the table base. The EKG cable exit point shall include a means (rubber grommet) to insure that the cable is protected from any sharp edges that may abrade the cable. Excess cable shall be looped back into the conduit or coiled in the table base. Insure that an above floor service loop is present that accommodates the full unrestricted movement of the patient table.

Cat5 Cable(s)

The under floor Cat5 cables are intended for remote user interfaces. At the workstation the Cat5 cables are connected to USB to Ethernet media converters. At the bedside the Cat5 cables are connected to Ethernet to USB media converters. The media converts provide USB 1.1 data connectivity and remote power (5V @ 500mA) for the bedside user interfaces. The bedside user interfaces are optional and they include a small joystick controller and/or a second remote control station. The Ethernet cables should be left under the floor if no additional bedside controllers are installed. If bedside controllers are include in the s5i installation then the Cat5 bedside cables should be routed through the table base or other acccessway so that the cable exits at the table base. The Cat5 cable exit point(s) shall include a means (rubber grommet) to insure that the cable is protected from any sharp edges that may abrade the cable. Excess cable shall be looped back into the conduit or coiled in the table base. Insure that an above floor service loop is present that accommodates the full unrestricted movement of the patient table.

Workstation Potential Equalization

An 8 AWG (3.26mm) green/yellow safety wire is included as part of the s5i 30 meter PIM cable assembly. This cable, when measured without any loops in the wire (loops add inductance), has an approximate impedance of ~0.06 ohm at 60Hz. This cable insures that the s5i workstation is at the same potential as the bedside protective earth. This safety wire mitigates the risk to the patient of excessive enclosure leakage currents resulting from different protective earth systems. The s5i workstation has a potential equalization post for connection to this safety wire. The bedside end of the safety wire is to be connected directly to the patient table protective earth bus bar or to the Angiography system protective earth star point. Insure that a 1 meter (3 feet) service loop is present at the s5i workstation. Excess safety wire should be removed (cut off) at the connection point to the patient table bus bar or the Angiography system protective earth star point to insure the lowest possible impedance of the safety wire.

WARNING:

Under no circumstance shall excess safety wire be coiled or looped. This results in an increase in the wire inductance and a corresponding increase in impedance. Excess wire length shall be removed

Chapter 5 Installation

The s5i system installation is performed by Volcano Corporation or other volcano certified installers. For specific wiring, cables and connections, please consult with your installation team.

Unpacking and Assembling the s5i

The s5i is shipped in multiple packages on a single pallet. The base system includes:

Central Processing Unit (CPU)
Isolation transformer
Patient Interface Module (PIM)
Control station
Control room LCD monitor (s5iGE only)
Required cabling
Patient Interface Module (PIM)
PIM holder
DVD-R Disk
Volcano s5i Operator's manual CD

Optional additional equipment may include:

Second control station
Control room LCD monitor
Control station bedside mounting hardware
Printer
Joystick
Video switch
Video amplifier/splitter
Video line driver

All packages should be inspected upon receipt. Inventory should be checked against the shipper and the installation work order. Contact Volcano Customer Service to resolve observed discrepancies or to report damaged materials.

Reviewing the Pre-Installation

Assess the adequacy of the s5i pre-installation preparation. Confirm the following:

- Adequate desktop space is available for the control room monitor and control station and any optional equipment. When necessary, the control room monitor can be mounted to the wall utilizing a swing arm.
- Sufficient floor space is available for s5i workstation and isolation transformer and the location does not obstruct the control room workflow.
- The intended s5i workstation location is within 2 meters of the control room monitor and control station.
- The intended s5i isolation transformer location is within 2.5 meters of an AC power outlet and within 0.5 meters (20 inches) of the s5i workstation intended location.
- The under floor s5i 30 meter PIM cable assembly is installed and the cable has a 1 meter (3 feet) service loop at the intended workstation location.

Installing the s5i Control Room Equipment.

Place the s5i workstation and isolation transformer in the designation location. Place the control room monitor and control station in the designation location. Place any optional equipment into their designated locations.

Isolation Transformer Fuse Selection

The fuse to be installed in the isolation transformer depends on the input voltage. Use the following table to determine which fuse to install.

100 Volts	8.0 Amp AT	Bussman part number S516-8A
120 Volts	6.3 Amp AT	Littlefuse part number 0213 6.3A
220-240 Volts	3.15 Amp AT	Littlefuse part number 0213 3.15A

Establish Control Room System Interconnections

Connect the system per the following diagrams. There are two control room diagrams. The Control Room Base Installation diagram includes all required elements to configure a fully functional s5i system. The Control Room Optional Equipment diagram includes all optional equipment that can be connected to the s5i system. For clarity, some of the base equipment connections are not shown in the second diagram.

Control Room Base Installation Wiring Diagram

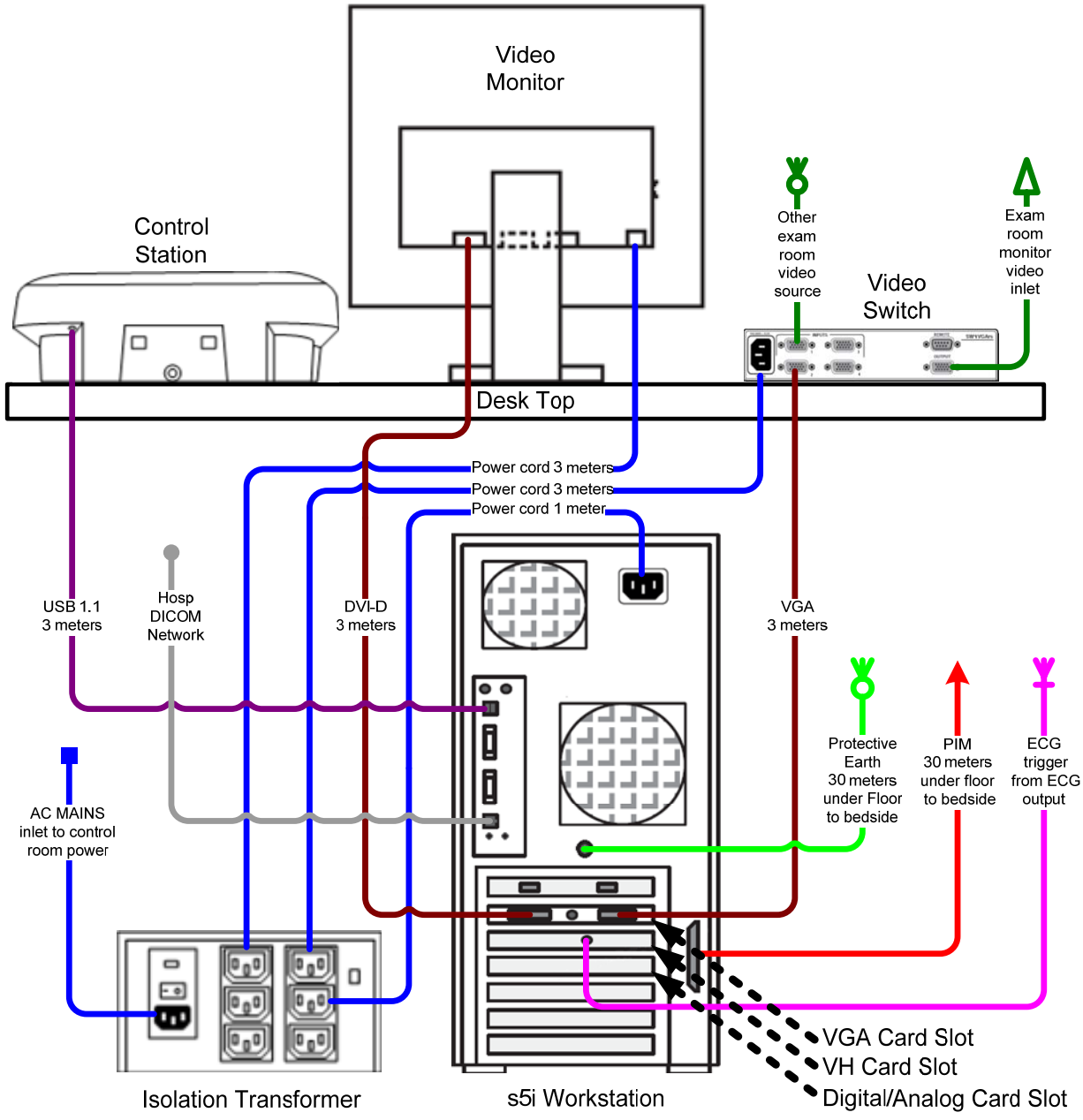


Figure 19 Control room Base Installation Wiring Diagram

Control Room Optional Equipment Wiring Diagram

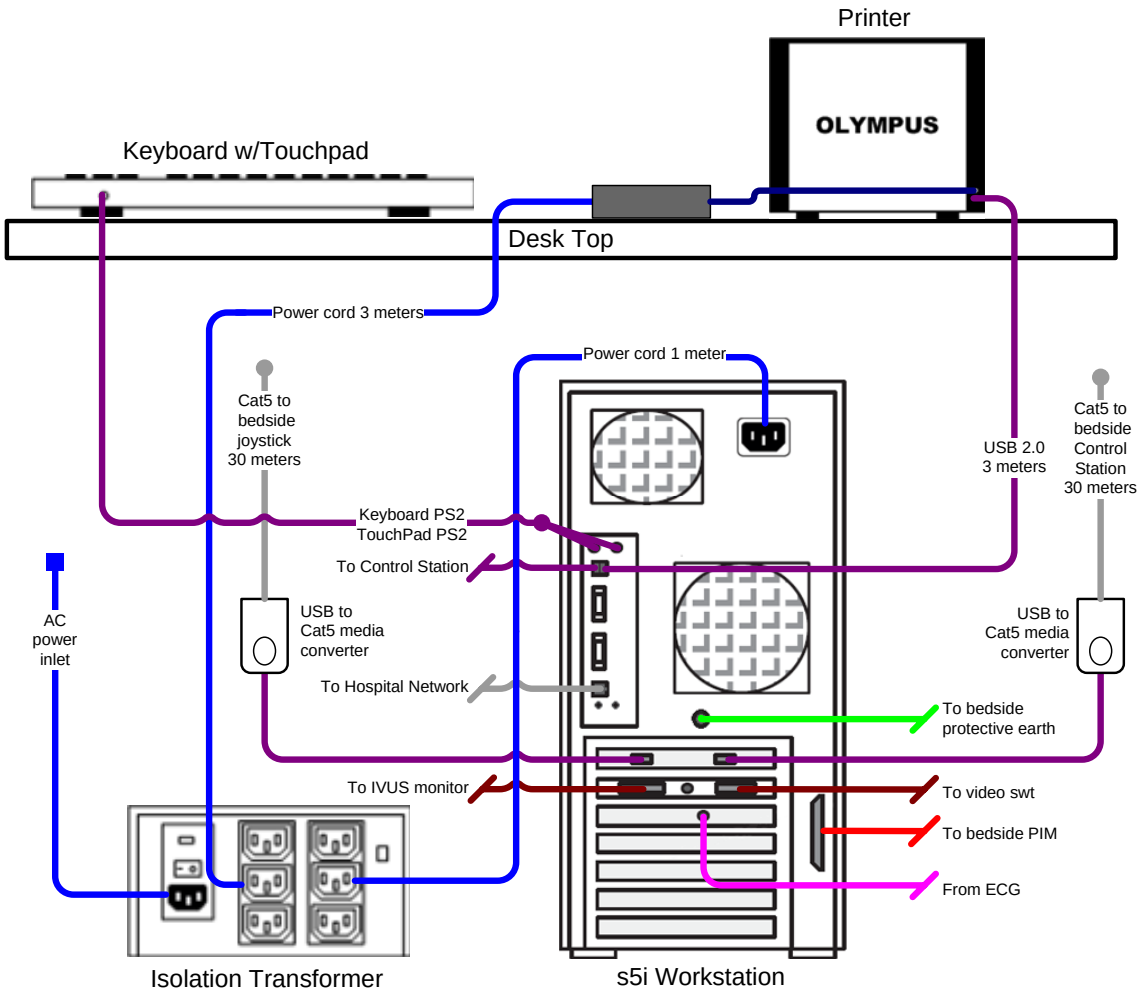


Figure 20 Control room option installation wiring diagram

Use the connection symbols to help you make the necessary connections.

Installing the s5i Exam Room Equipment

The exam room equipment includes both required and optional equipment. An exam room monitor, the Patient Interface Module (PIM) and its associated mounting hardware are all required. The optional exam room equipment includes the peripheral controllers (control station and/or joystick.)

The PIM is always located at the bedside within the patient environment.

The exam room monitor is located within the patient environment.

The control station can be located on the bedside rail (within the patient environment ≤1.5 meters from the table) or outside the patient environment.

The joystick is always located on the bedside rail within the patient environment.

CAUTION: When either the joystick or the control station is located within the patient environment the protective earth connection (green/yellow wire) must be connected to the exam room protective earth system.

PIM installation

The PIM is cable is routed under the floor from the s5i workstation to the bedside. The cable should be installed per the pre-installation instructions (see above.) The PIM is normally stored in the PIM Holder but can also be affixed to any ferrous metal surface using the magnet strip on the back of the PIM housing.

PIM Holder

The PIM holder should be position on the bedside rail to avoid interfering with the normal catheter laboratory work flow. The PIM holder is designed to swivel so that it easily moves out of the way when a rolling patient bed is moved to the Angiography table for patient transfer. The PIM holder is mounted to the bedside rail using a quick release mount. To install the rail mount, depressing the lock mechanism on the back of the mount and swiveling it onto the rail in the desired position. The PIM can now be inserted into the PIM holder.

Bedside Control Station

The Control Station can optionally be mounted onto the bed rail using the Volcano Control Station bedside rail mounting kit. When the control station is mounted to the bedside rail the provided green/yellow safety ground wire must be permanently affixed to the back of the Control Station using an Allen head screw (provided on back of Control Station.)

CAUTION: The control station green/yellow ground wire must be connected to the bedside protective earth (ground) system in order to insure patient safety.

The Control Station 3 meter USB cable is mated to the Cat5 to USB media converter. The media converter should be mounted under the table in a secure manner using tie wraps and tie wrap tie down blocks. The USB and ground wires should be routed together in a manner that provides an adequate service loop. The service loop must allow full movement of the table. After installing any bedside rail mounted peripheral, insure free and full table motion in all axis.

Bedside Joystick

The Joystick is mounted to the bed rail. The Joystick green/yellow safety ground wire must be permanently affixed to the bedside protective earth (ground) system.

CAUTION: The control station green/yellow ground wire must be connected to the bedside protective earth (ground) system in order to insure patient safety.

The Joystick 3 meter USB cable is mated to the Cat5 to USB media converter. The media converter should be mounted under the table in a secure manner using tie wraps and tie wrap tie down blocks. The USB and ground wires should be routed together in a manner that provides an adequate service loop. The service loop must allow full movement of the table. After installing any bedside rail mounted peripheral, insure free and full table motion in all axis.

Bedside ECG connection

The s5i system relies on a ECG signal to identify frames for VH processing. Therefore the s5i system must be connected to a patient isolated ECG signal. In many installation the ECG signal is available in the control room and the provided 5 meter ECG cable should be used. When the ECG signal is not available within the control room, then the 30 meter under floor ECG cable must be used. The ECG under floor cable is terminated in a twin axial connector. This connector mates to a 3 meter adapter cable which interfaces to the bedside ECG system. There are a variety of adapter cables to interface to the different ECG systems on the market. Consult Volcano customer/field service to select the appropriate adapter cable for your installation.

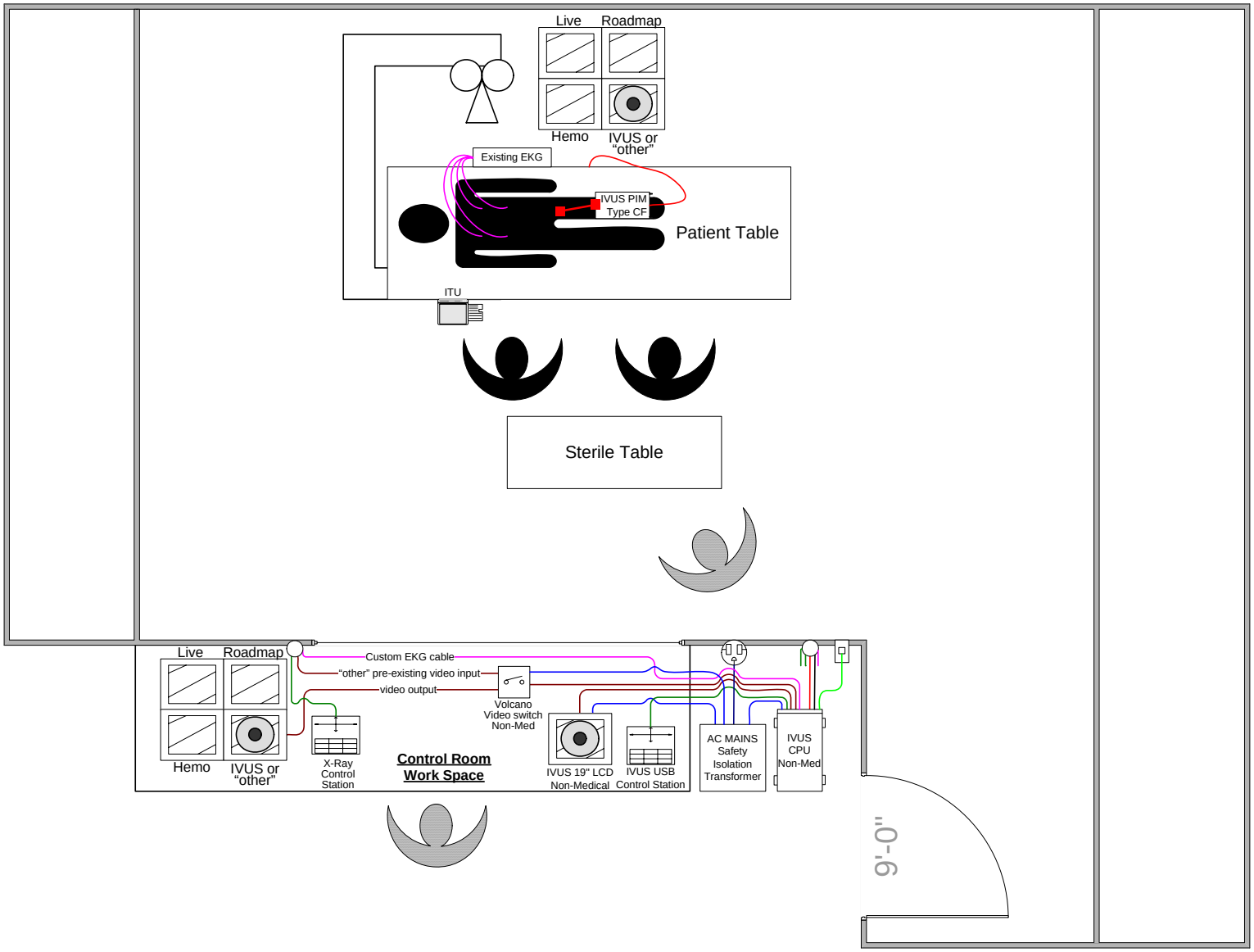


Figure 21 Physical layout base configuration

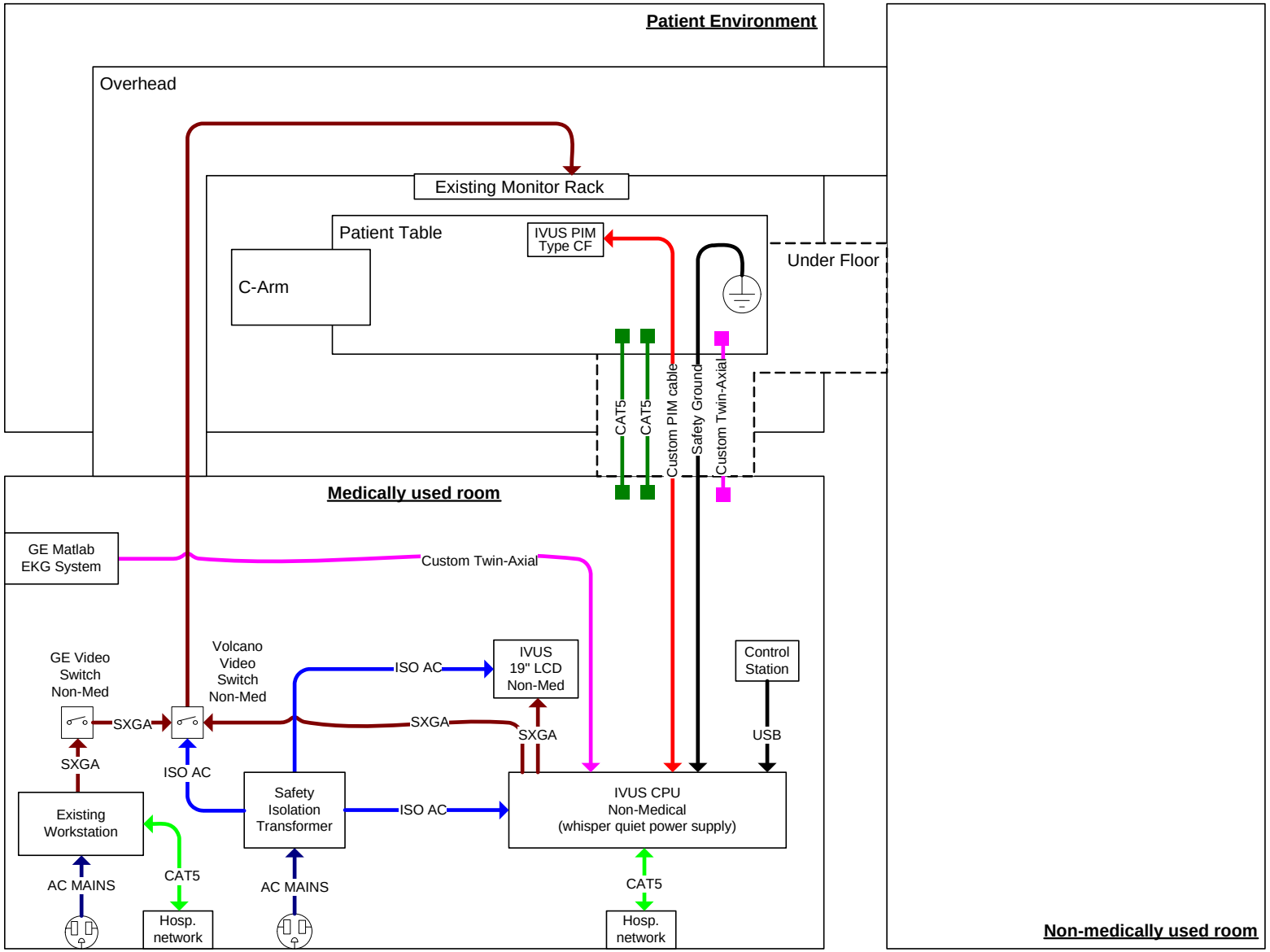


Figure 22 Wiring diagram base configuration

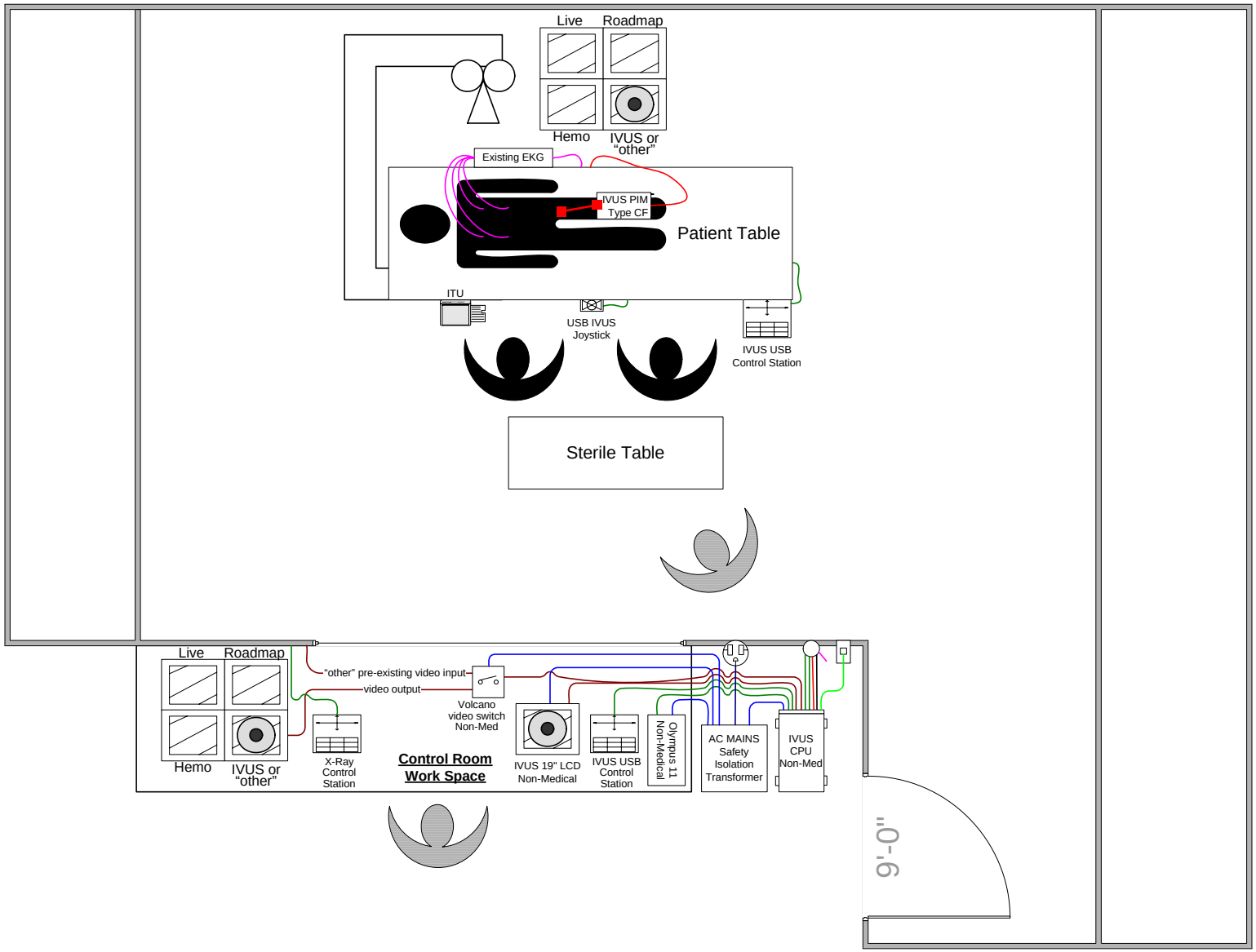


Figure 23 Physical layout with all options (less keyboard)

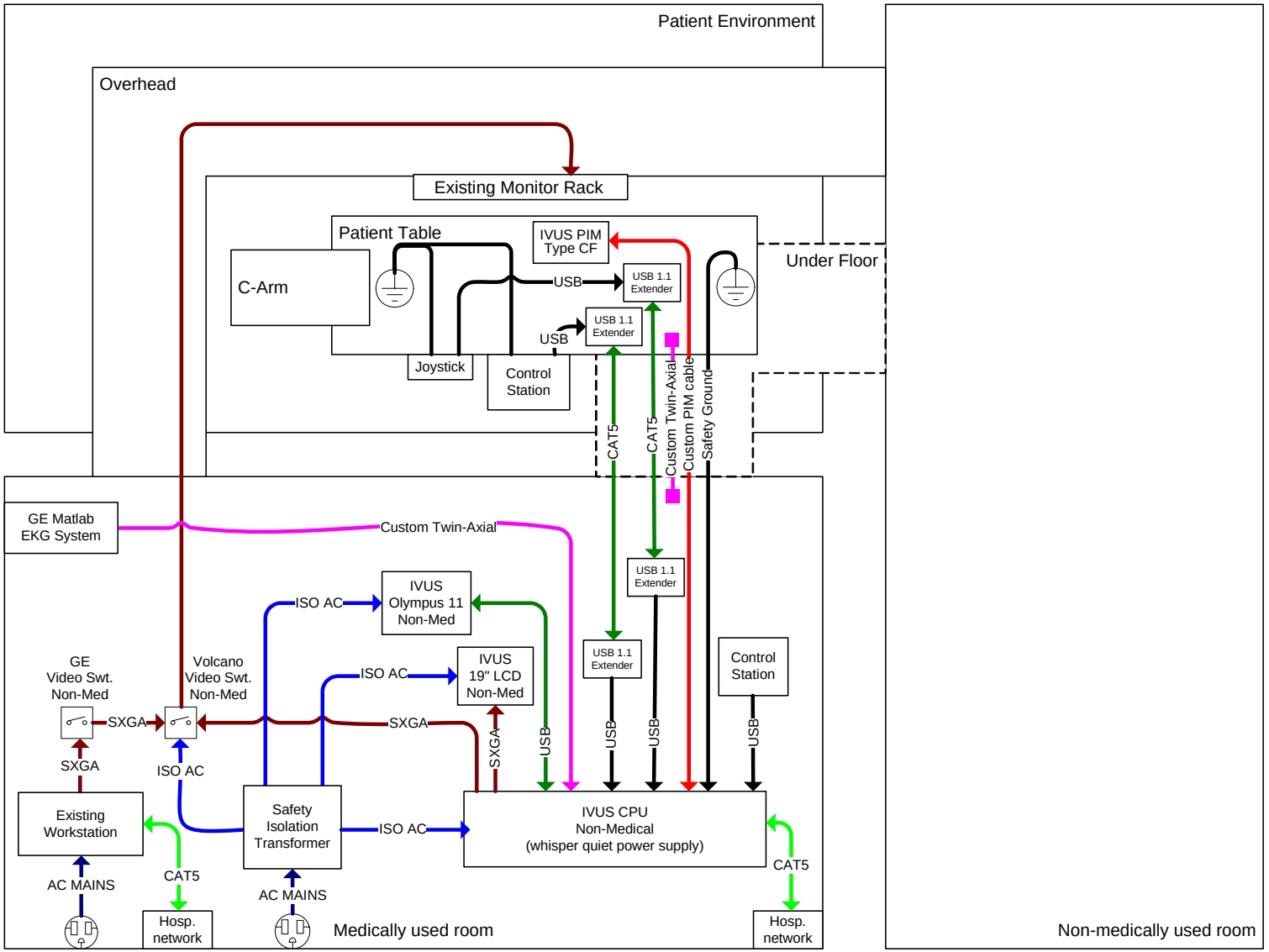


Figure 24 Wiring Diagram all options (less keyboard)

First Power on Procedure

The s5i system should be powered up after all equipment is connected with the exception of the Printer. The printer will be installed and configured after first power up.

1. Insure that all intended cables are connected (except the printer USB cable) within the system per the previous wiring diagrams.
2. Energize the s5i workstation by depressing the power on switch on the front of the workstation.
3. Load the physician names into the Physician drop down list if known.

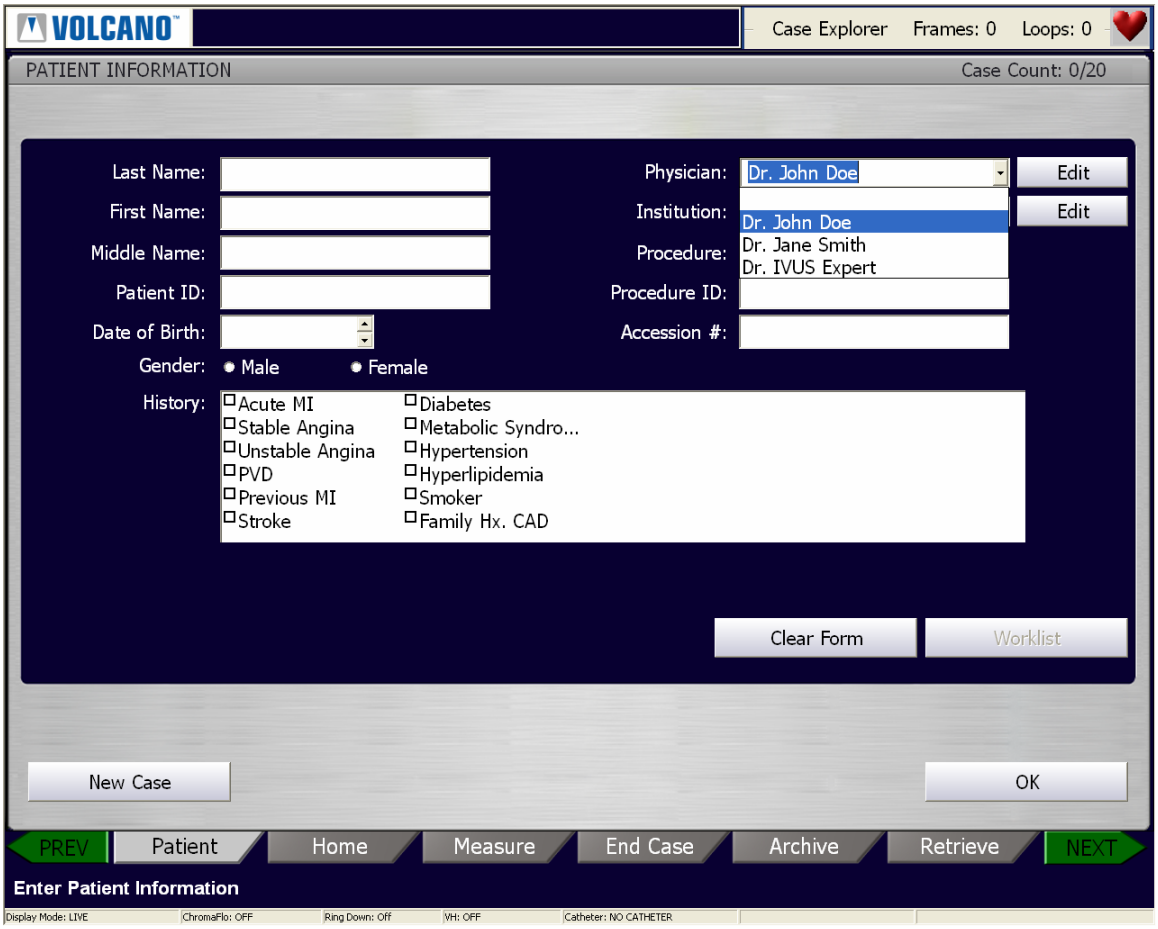


Figure 25 Patient Menu -> Load Physician Names

4. Enter the institutions name in the drop down box.

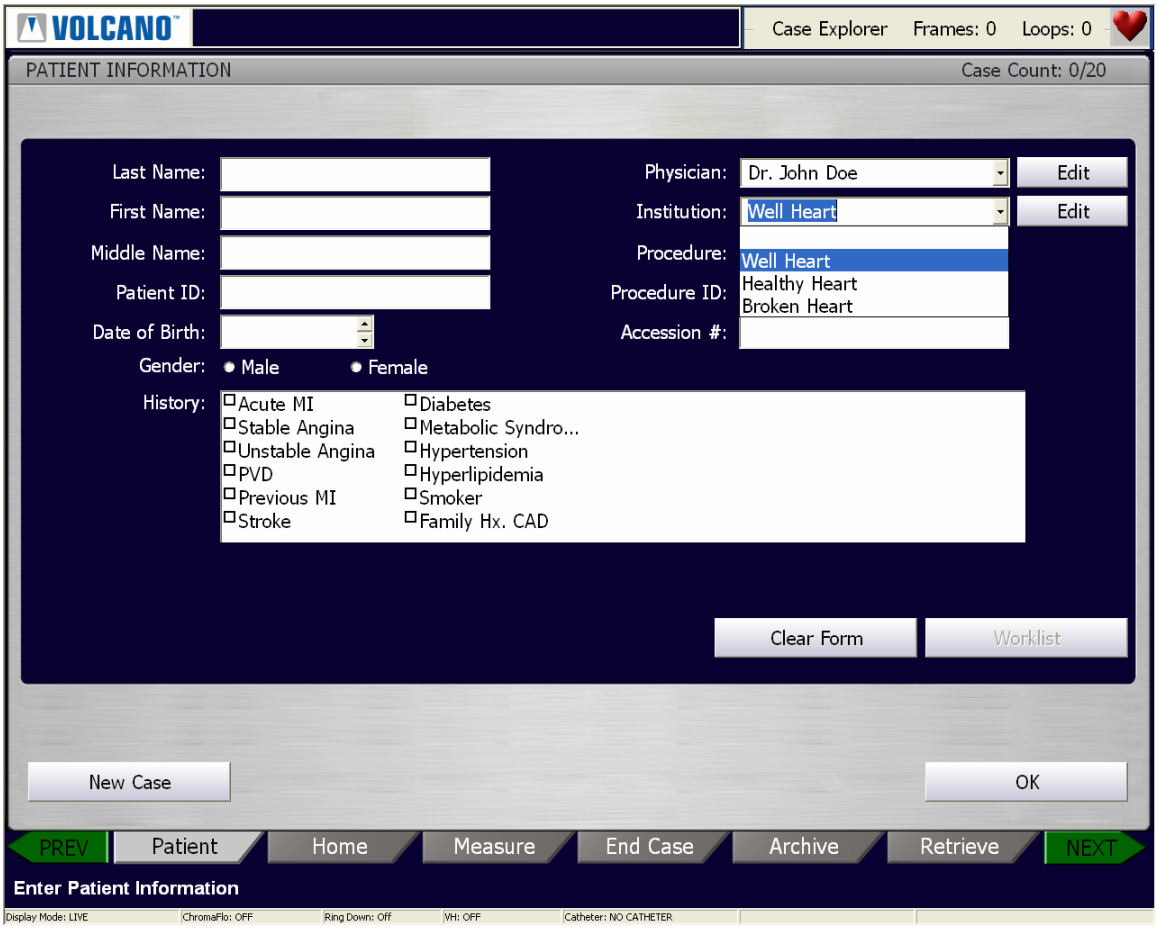


Figure 26 Patient Menu -> Load Institution Names

5. Set the system settings per the Institutions preference if known. The default settings are adequate for most installations. Refer to Chapter 6 System Settings section for information on the available system settings.
6. Set the date/time and date format.

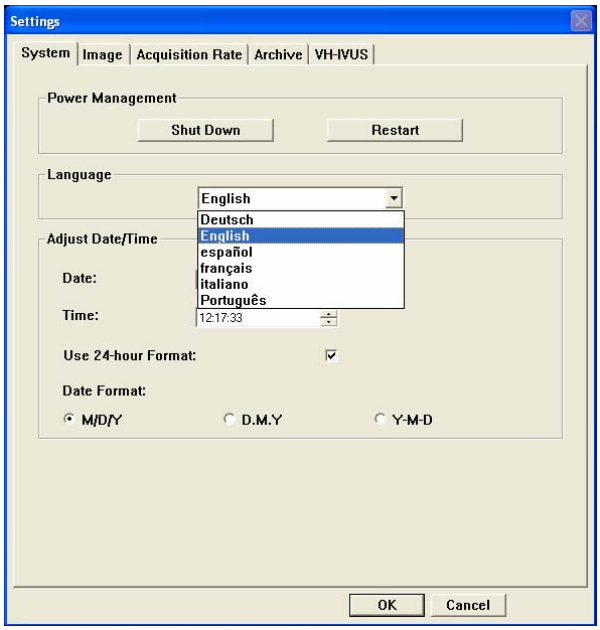


Figure 27 System Settings select Language

7. Set the preferred language.
8. Configure the DICOM network interface per the local IT requirements. Refer to section 6 and Appendix B when configuring the DICOM network interface.
9. Adjust the system mouse speed.
10. Login to Field Service Dialog.
11. Open the Field Service Dialog (CTRL+ALT+S), press **Yes** (you are sure).
12. Press the Utility tab.
13. Log into the Advanced user's Service Menu (see Appendix A).
14. Enter **fieldservice** and **eson**.
15. Press the Sign in button.
16. Turn **off** Deep Freeze (see Appendix A).
17. Press the Windows Explorer button.
18. Navigate to C:\FieldService
19. Double-click on Tools.exe.
20. Click on DF OFF.
21. System will restart.
22. Log into the Advanced user's Service Menu (see Appendix A)
23. Enter **fieldservice** and **eson**.
24. Press the Sign in button.
25. Press the Control Panel button.

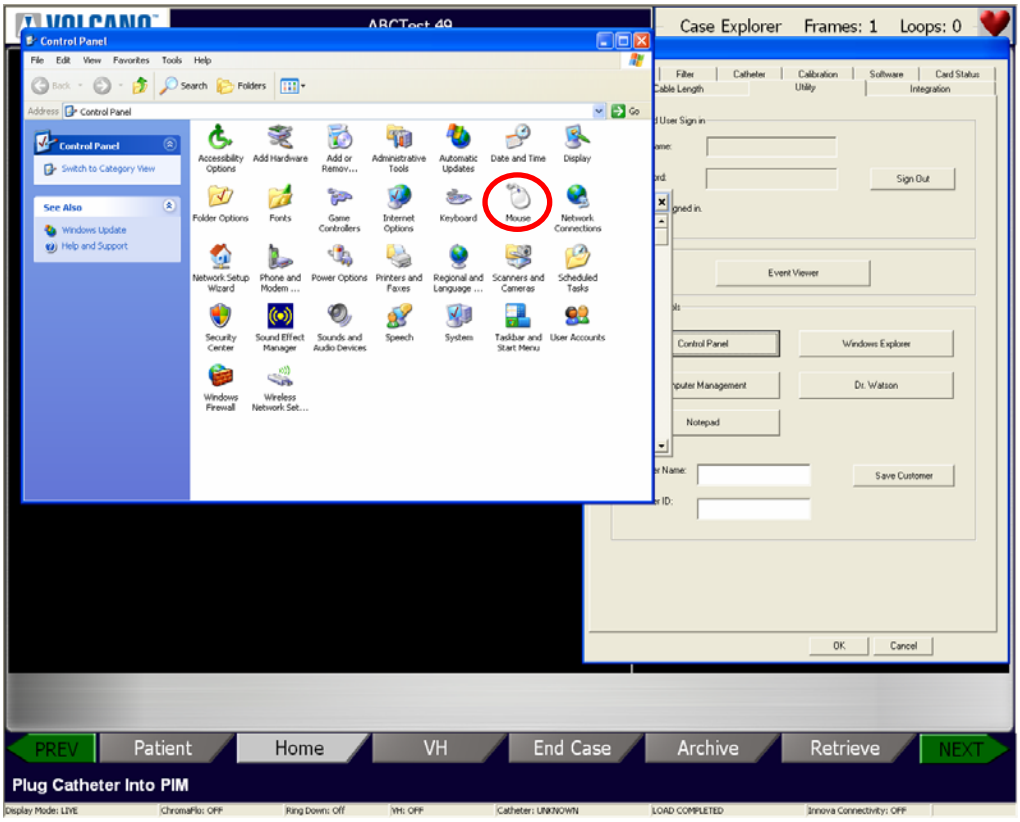


Figure 28 Control Panel -> Select configure Mouse

26. Double-click on Mouse.
27. Press the Pointer Options tab.
28. Ensure that Motion, Select a pointer speed is set to one position to the right of center.

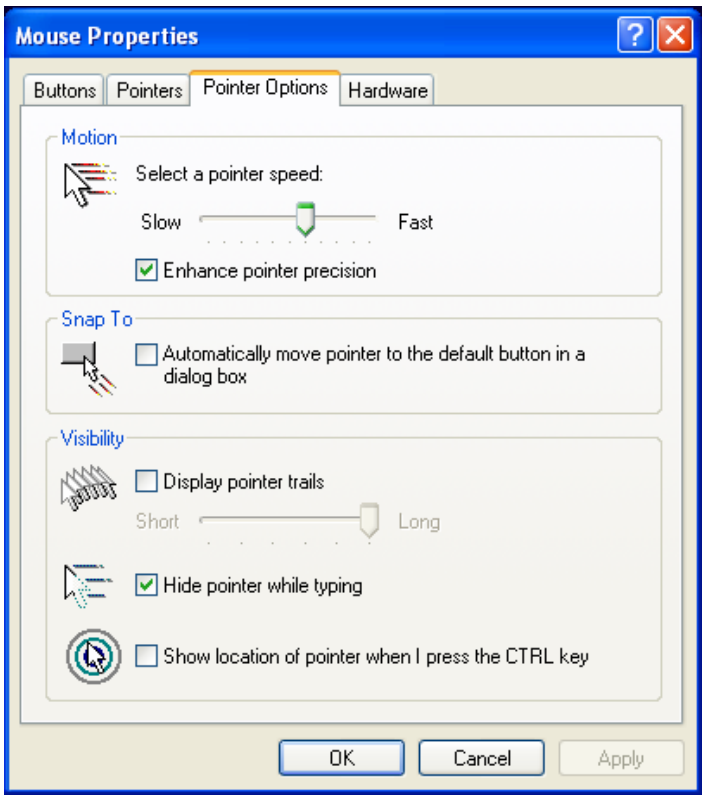


Figure 29 Mouse Properties -> Select Pointer Speed

29. Press OK.
30. Close the Control Panel.
31. Set Customer Name, Customer ID.
32. Click on the Utility tab of the Field Service Dialog.
33. Set the Customer Name and Customer ID.

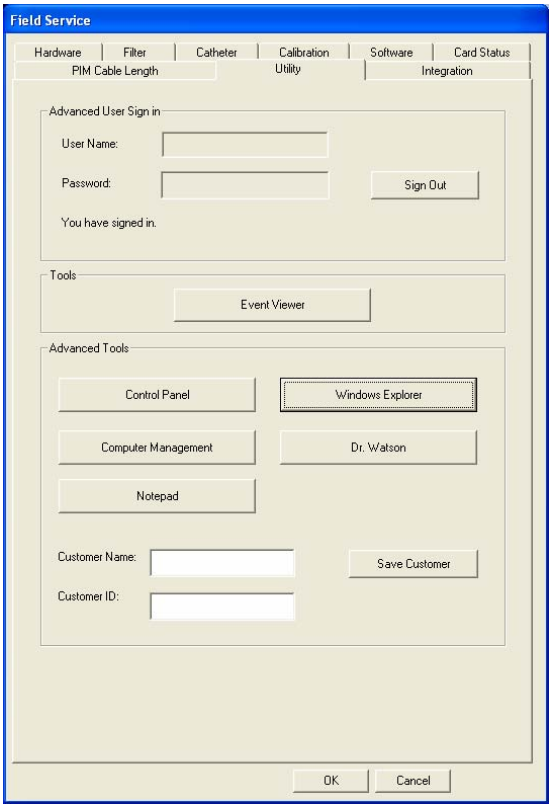


Figure 30 Service Menu -> Set Customer Name and ID

34. Configure PIM Cable length.
35. Click on the PIM Cable Length tab of the Field Service Dialog.

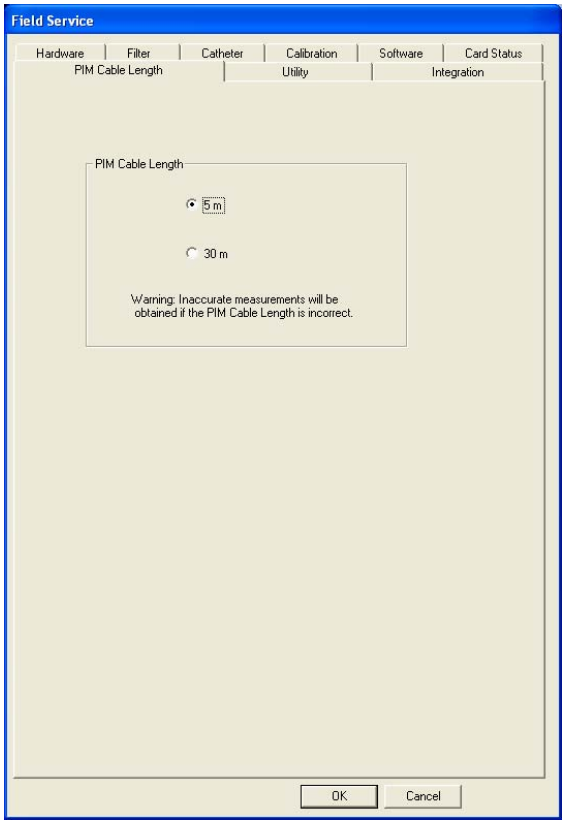


Figure 31 Advanced User Field Service Menu -> Select PIM cale length

36. Ensure that the selected PIM cable length matches the PIM cable installed with this system.

CATUTION: Incorrect PIM cable length settings can result in incorrect measurements. All under floor cables utilize the 30 meter PIM cable length. All above floor installations utilize the 5 meter PIM cable length.

37. Press the OK button to persist the PIM cable length setting.
38. Turn on Deep Freeze
39. Press the Windows Explorer button.
40. Navigate to C:\FieldService
41. Double-click on Tools.exe
42. Click on DF On.
43. System will restart. Use **End Now** to stop any program that will not exit.
44. Reboot the system and install the optional printer (see below) if required.

P11 Printer Installation and Configuration Procedure.

The Olympus P11 Printer is an optional color photo printer. Please refer to Appendix H Manufacturer's User's Guide for hardware installation instructions. The following steps should be followed:

1. Unpack and remove all shipping materials from the P11 Printer,
2. Remove the side panel and install the USB and power cables,
3. Open the printer paper tray, remove the 3"x5" insert and install the 4"x5" paper,
4. Install the ink cartridge that comes in the box with the printer,
5. Plug the power supply into the isolation transformer.

The ink cartridge included in the P11 shipping box contains only enough ink to test the printer. After installation confirmation, the ink cartridge should be replaced with the one included in the installation kit.

Connecting and Setting up the Printer

1. If connected, disconnect the USB cable from the Printer to the s5i workstation.
2. Login to Field Service Dialog.
3. Open the Field Service Dialog (CTRL+ALT+S), press Yes (you are sure).
4. Press the Utility tab.
5. Log into the Advanced user's Service Menu (see Appendix A).
6. Enter **fieldservice** and **eson**.
7. Press the Sign in button.
8. Turn **off** Deep Freeze (see Appendix A).
9. Press the Windows Explorer button.
10. Navigate to C:\FieldService
11. Double-click on Tools.exe
12. Click on DF OFF.
13. System will restart.
14. Log into the Advanced user's Service Menu (see Appendix A).
15. Enter **fieldservice** and **eson** in the login screen.
16. Press the Sign in button.
17. Plug the printer's USB cable into an available USB port.
18. Turn the printer on, ensure that the green LED next to the Power button is lit.
19. The New Hardware Wizard dialog will begin.

Found New Hardware Wizard
Welcome to the Found New Hardware Wizard
Windows will search for current and updated software by looking on your computer, on the hardware installation CD, or on the Windows Update Web site (with your permission).
Read our privacy policy
Can Windows connect to Windows Update to search for software?
Yes, this time only
Yes, now and every time I connect a device
No, not this time
Click Next to continue.
< Back
Next >
Cancel

Figure 32 Found New Hardware Wizard -> Search for Software

20. Select **No, not at this time**.
21. Press **Next**.

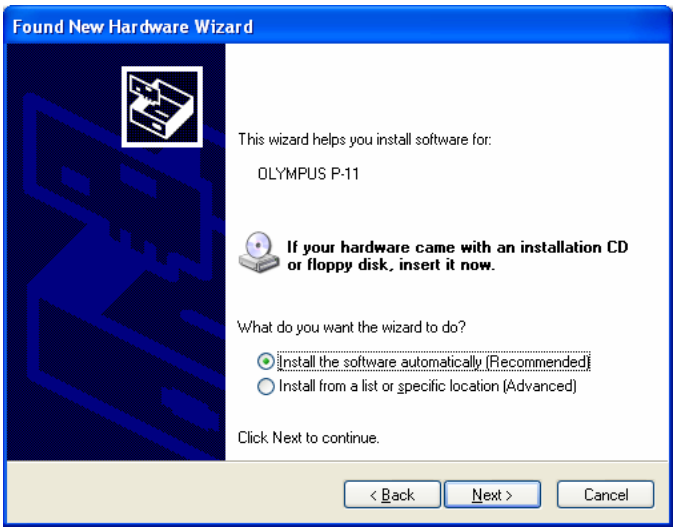

Found New Hardware Wizard
This wizard helps you install software for:
OLYMPUS P-11
If your hardware came with an installation CD or floppy disk, insert it now.
What do you want the wizard to do?
Install the software automatically (Recommended)
Install from a list or specific location (Advanced)
Click Next to continue.
< Back
Next >
Cancel

Figure 33 Found New Hardware Wizard -> Install the Software

22. Select Install the software automatically.
23. Press **Next**.

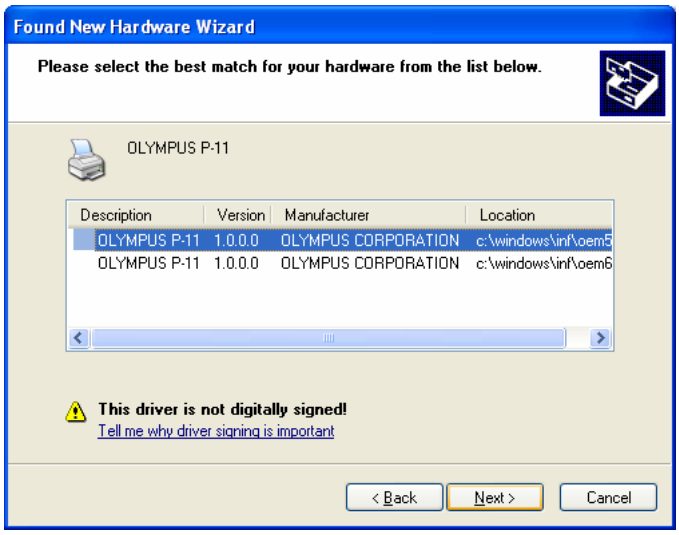

Found New Hardware Wizard
Please select the best match for your hardware from the list below.
OLYMPUS P-11
Description
Version
Manufacturer
Location
OLYMPUS P-11 1.0.0.0 OLYMPUS CORPORATION c:\windows\inf\oem5
OLYMPUS P-11 1.0.0.0 OLYMPUS CORPORATION c:\windows\inf\oem6
This driver is not digitally signed!
Tell me why driver signing is important
< Back
Next >
Cancel

Figure 34 Found New Hardware Wizard -> Select the Software

24. Select the first driver listed.
25. Press **Next**.

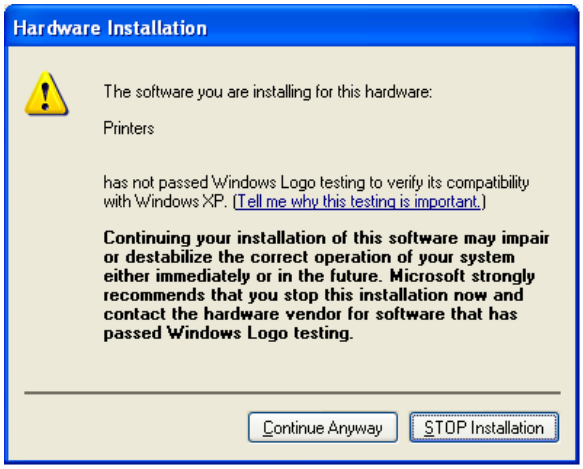

Hardware Installation
The software you are installing for this hardware:
Printers
has not passed Windows Logo testing to verify its compatibility with Windows XP. (Tell me why this testing is important.)
Continuing your installation of this software may impair or destabilize the correct operation of your system either immediately or in the future. Microsoft strongly recommends that you stop this installation now and contact the hardware vendor for software that has passed Windows Logo testing.
Continue Anyway
STOP Installation

Figure 35 Found New Hardware Wizard -> Compatibility

26. Press **Continue Anyway**.

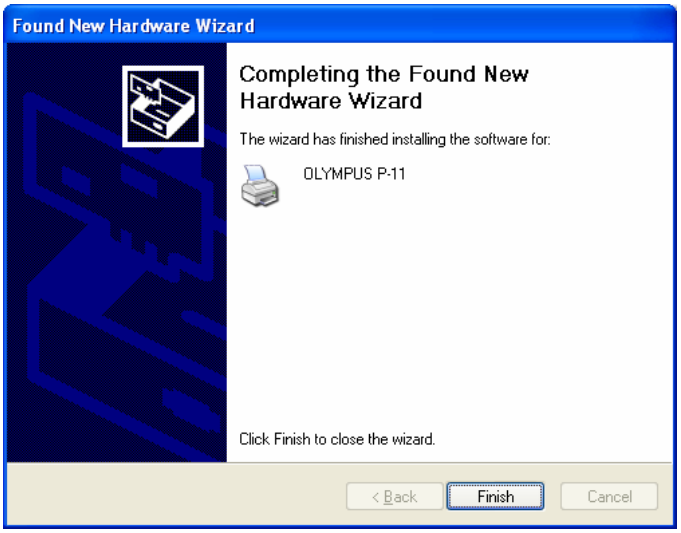


Figure 36 Found New Hardware Wizard -> Finish

27. Press **Finish**.
28. Press the Control Panel button.

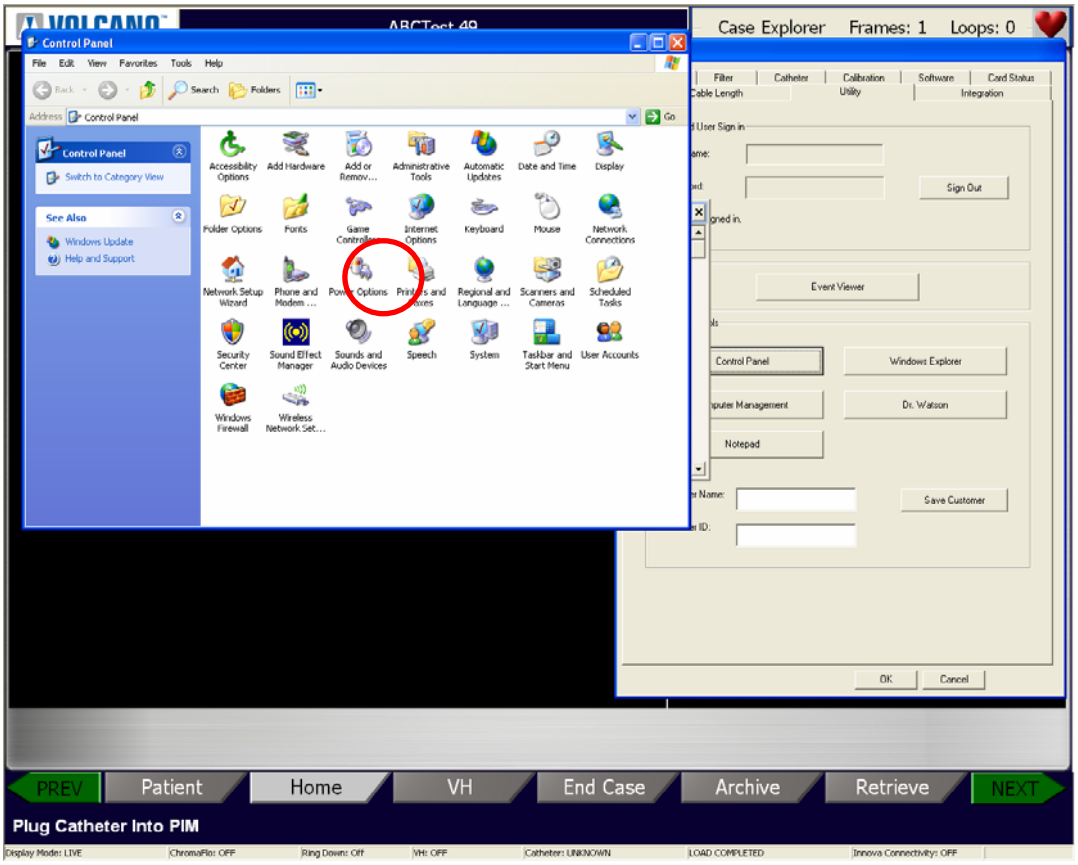


Figure 37 Control Panel -> Printers and Faxes

29. Double-click on **Printers and Faxes**

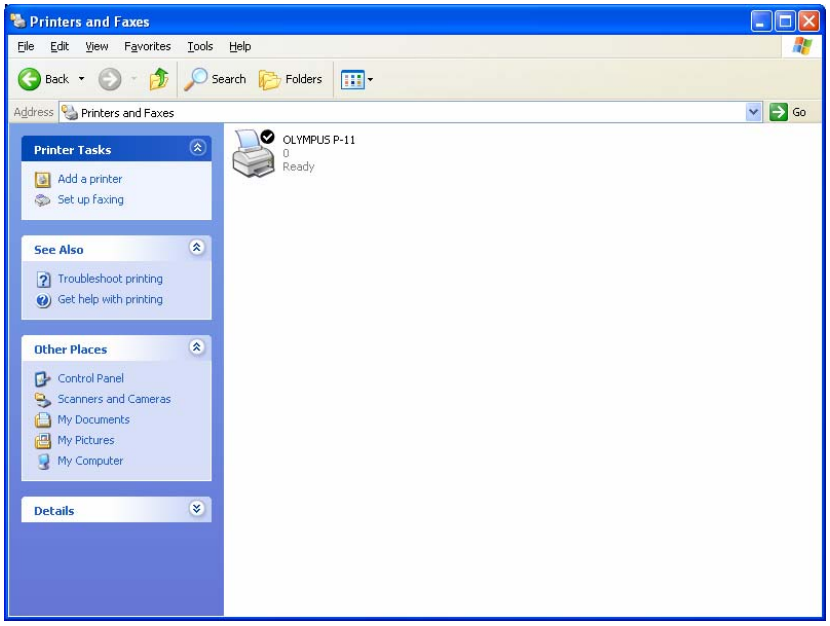


Figure 38 Printers and Faxes -> Olympus P-11

30. Right-click on OLYMPUS-P11 and Select **Printing Preferences**.

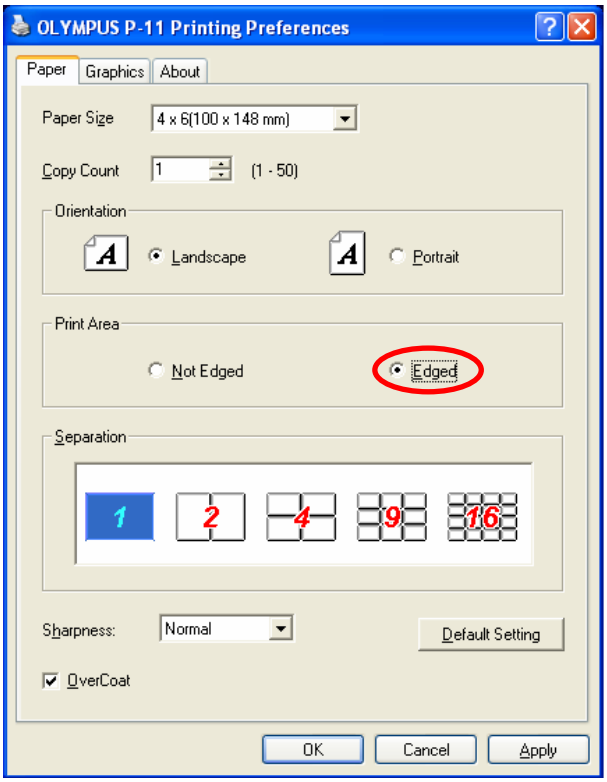


Figure 39 Olypus P11 Printing Preferences -> Edged

31. Ensure that **Print Area Edged** is selected.
32. Press **OK**.
33. Turn **on** Deep Freeze

34. Press the Windows Explorer button.
35. Navigate to C:\FieldService
36. Double-click on Tools.exe
37. Click on DF On.
38. System will restart.
39. Print a test page
40. Confirm that the entire image is present on the print and that an outer white border is present around the print.
41. Replace the print cartridge used during testing (the one that comes with the printer) with the print cartridge in the installation kit.

GE INNOVA Connectivity Configuration Procedure

This section contains the installation procedure for enabling the GE Innova connectivity feature.

Loading ITU Software for s5i connectivity

In order to enable the ITU connectivity feature the ITU software must be updated using the ITU software distributed on the s5i service disk. Refer to GE service note sn4620 INNOVA 2100IG TSM3 UPGRADE PROCEDURE.pdf or CNF0091 – Intelligent Touch Screen Unit (ITU) configuration for installation instructions.

1. Confirm that the ITU software has been updated according to the approved GE procedures.
2. Confirm that the Innova DL has the Innova IVUS compatible software loaded.
3. Login into Field Service Dialog on the s5i.
4. Open the Field Service Dialog (CTRL+ALT+S), press Yes (you are sure).
5. Press the Utility tab.
6. Log into the Advanced user's Service Menu (see Appendix A)
7. Enter **fieldservice** and **eson**.
8. Press the Sign in button.
9. Enable the GE Innova Interface
10. Tab to the Integration tab on the Advanced User's Service menu

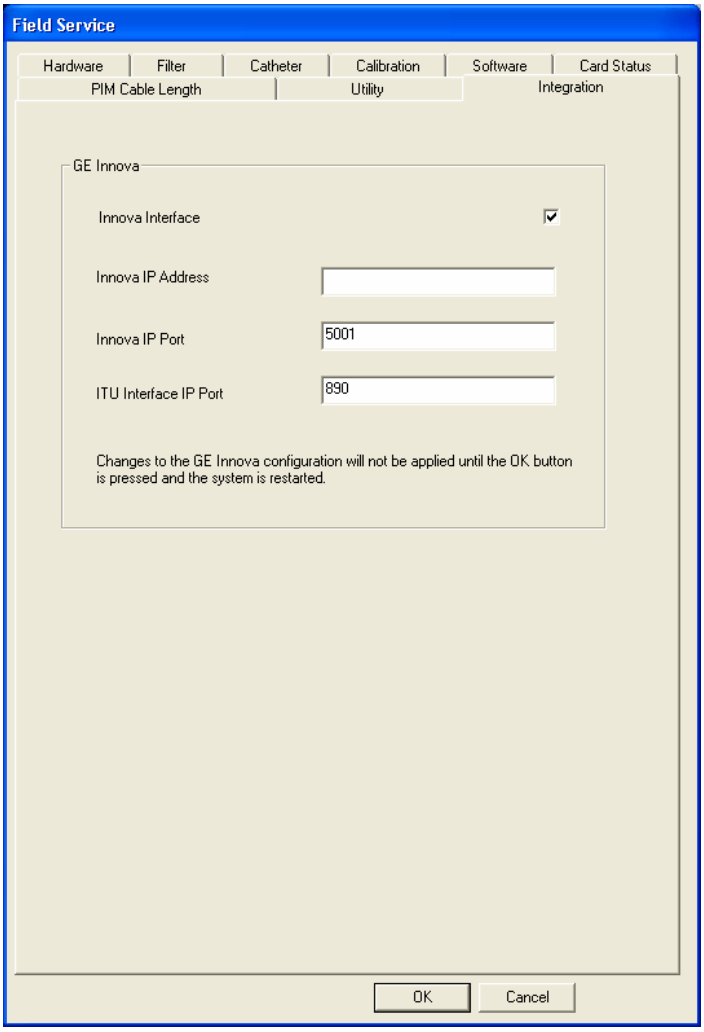


Figure 40 s5i Integration Page

11. Enable the Inoval Interface by checking the Innova Interface box under the GE Innova dialog window.
12. Enter the Innova IP Address.
13. Enter the Innova Port Address.
14. Enter the ITU Interface IP Port Address.
15. Press **OK.**
16. From the Innova DL load an active patient file with a unique test name.
17. At the Inova ITU confirm that the IVUS tab is enabled.
18. On the s5i display, confirm that the active patient name on the s5i Patient screen matches the name loaded into the Innova DL.

CAUTION: To avoid incorrectly connecting the s5i to the wrong Innova system and ITU insure that the name loaded into the Innova DL is a unique test name.

Chapter 6 Software Re-Installation

Operating Software Overview

The s5i software environment is Microsoft Windows XP Pro. The Volcano s5i proprietary software application supports real time IVUS gray scale imaging, automatic boarder detection and simultaneous VH (tissue characterization) processing.

s5i with VH Description

The Volcano s5i is an IVUS (intravascular ultrasound) system including ChromaFlo. s5i VH is used for qualitative and quantitative evaluation of vascular morphology. It allows assessment of: vessel wall morphology, lumen characteristics, thrombus formation, delineates arterial walls and wall thickness using an imaging catheter. In addition, it allows for measurement of lumen diameter, vessel thickness, cross-sectional areas and, with the In-Line Digital feature, longitudinal measurements.

s5i Software Installation

The s5i and s5i/GE systems ship will fully loaded and configured software. The software installation procedure does not need to be executed during a new system installation unless anomalous behavior is encountered.

The system settings are based on user preferences and hospital IT infrastructure requirements. The s5i systems ships with default imaging settings that are intended to meet the majority of end user preferences. The IT infrastructure settings are not pre-configured as they vary from institution to institution. For a normal installation, skip this section and proceed directly to System Settings on page 104.

Preparation and Power Up

1. Complete the system installation per the Installation instructions defined in chapter 5
2. Gently pull on the keyboard to expose the keyboard.
3. Press the power switch on the front of the CPU to turn the system on.

Saving System Settings

1. The s5i software installation process involves re-ghosting the operating system and installing a fresh copy of the s5i application.

WARNING:

Prior to performing a software installation all system settings must be recorded and all patient data archived. The patient data can be either archived to DVD media or to the local PACS system.

2. Archive any patient data that has not been previously saved.
3. Record the system settings using the PDF form.
4. Open the PDF file Capture System Setting Form Appendix F.pdf on a service computer (not on the s5i system).
5. Complete the form and save it to the local hard drive.
6. The form will be used later in the procedure to manually re-install the system settings.

.Set/Confirm System BIOS settings

1. Press the settings button on the s5i control station and shut down the system.
2. Re-boot the system by depressing the CPU power on button on the front of the CPU.
3. Hit the Delete (Del) key when the Supermicro boot screen appears.

Figure 41 Supermicro Boot Screen

4. If you are prompted for a password, enter **eson**.
5. Use the Arrow keys and open the Main tab.

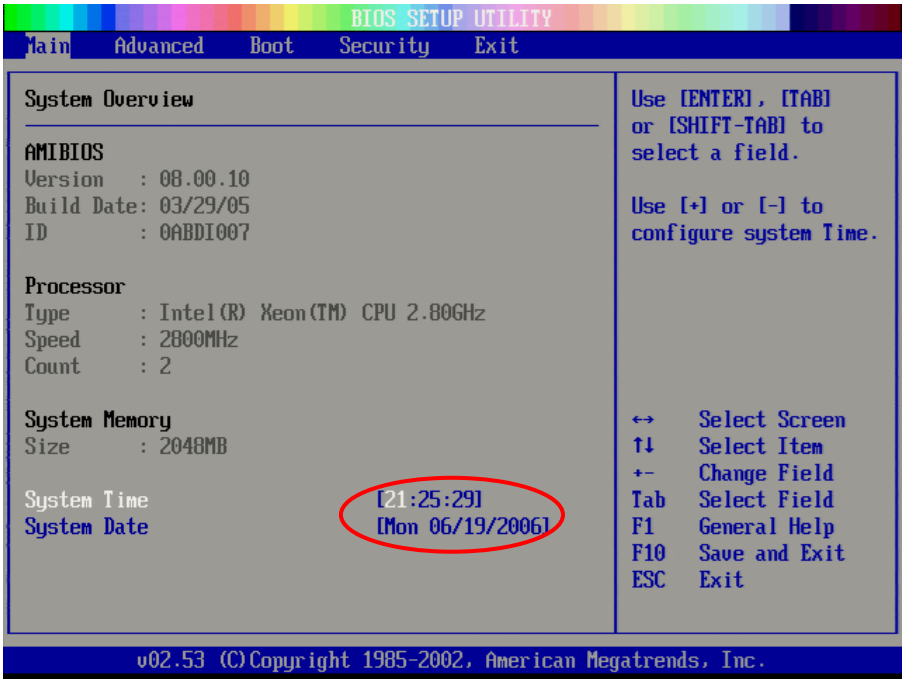


Figure 42 Main Tab

6. Ensure that the System Date and System Time are correct.
7. Press the Right Arrow key to open the Advanced tab.

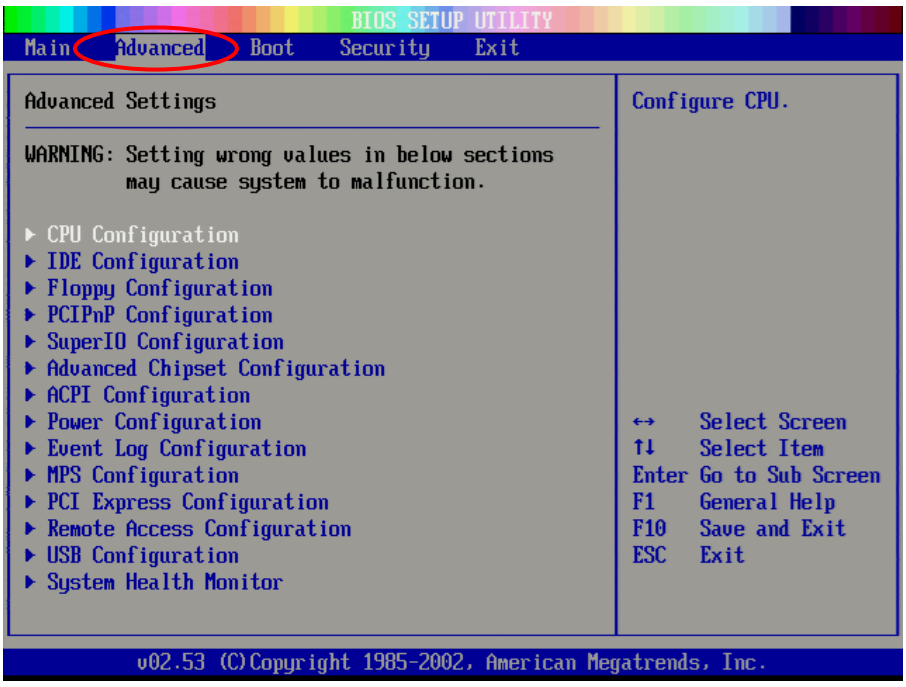


Figure 43 Advanced Tab

8. Use the Up and Down Arrow keys to highlight CPU Configuration.

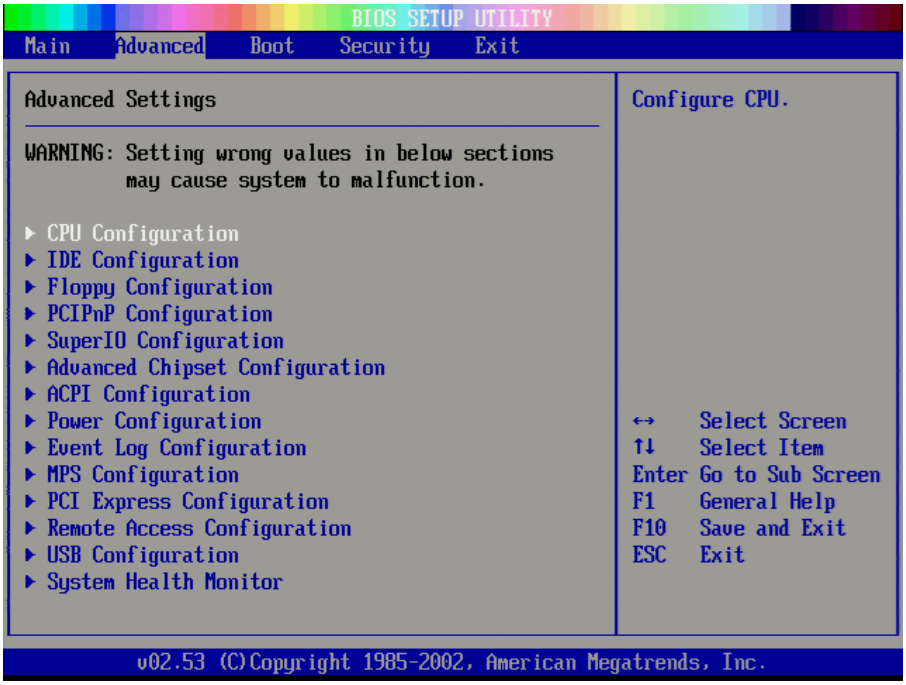


Figure 44 Advanced Tab CPU Configuration

9. Press the Enter key.
10. Ensure that Hyper-Threading Function is Enabled.

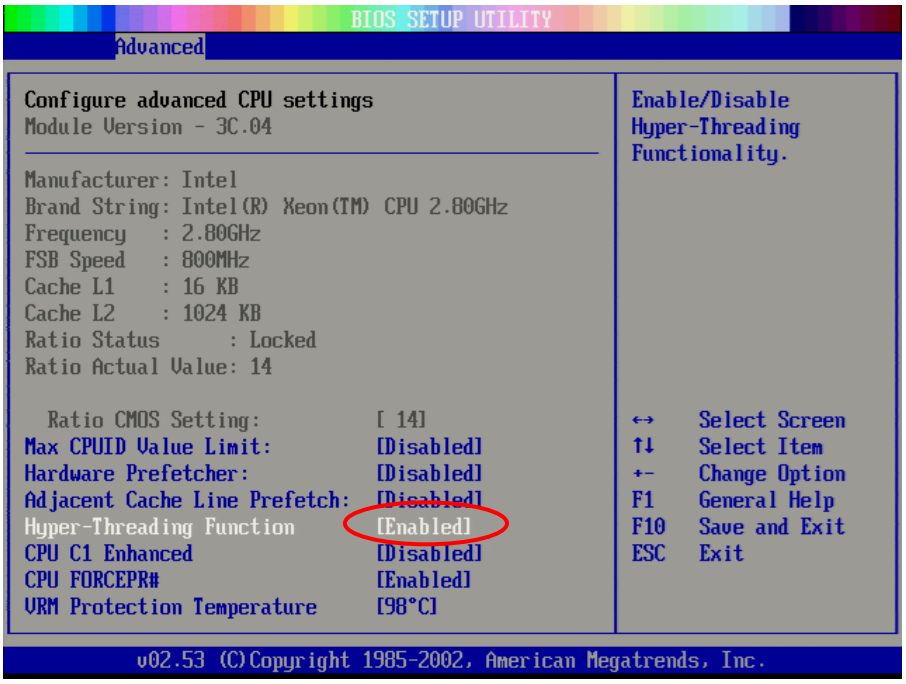


Figure 45 Advanced Tab –> Hyper Threading -> Enabled

11. Press the Esc key.
12. Use the Up and Down Arrow keys to highlight IDE Configuration.

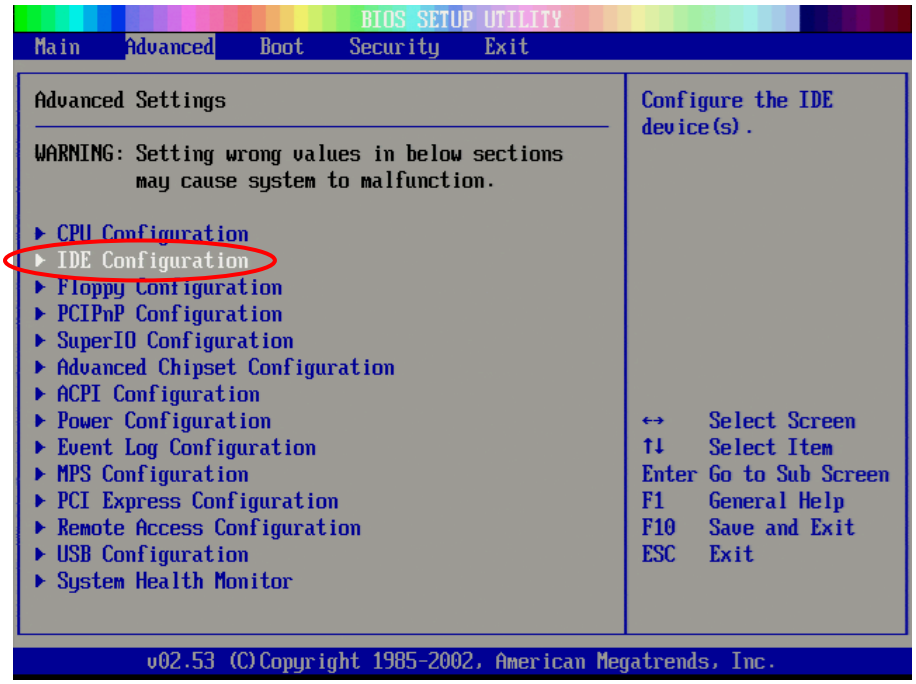


Figure 46 Advanced Tab –> IDE Configuration

13. Press the Enter key.
14. Ensure that Combined Mode Option is S-ATA 1st Channel.

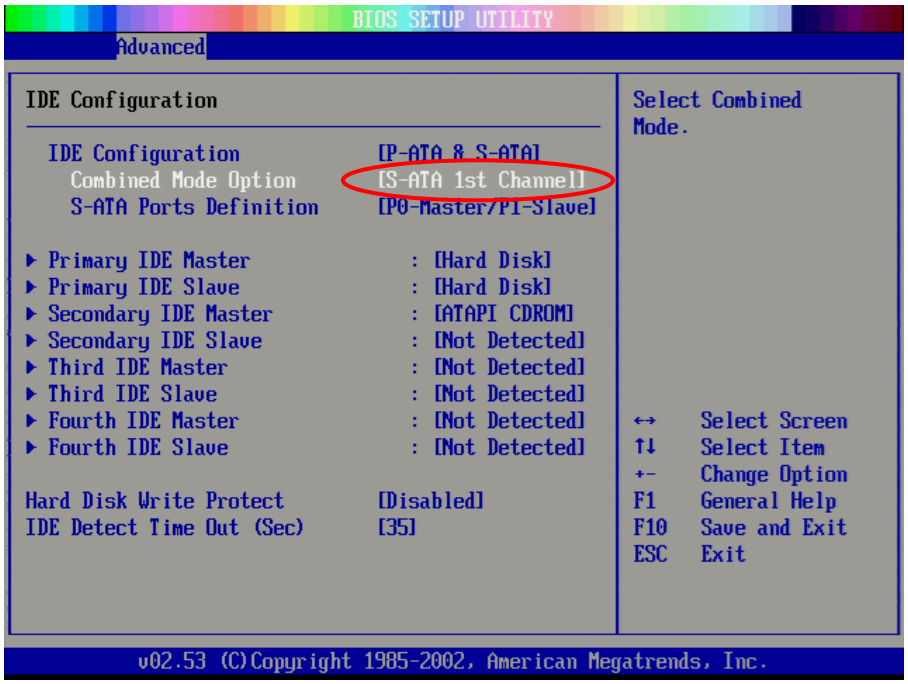

BIOS SETUP UTILITY
Advanced
IDE Configuration
IDE Configuration [P-ATA & S-ATA]
Combined Mode Option [S-ATA 1st Channel]
S-ATA Ports Definition [P0-Master/P1-Slave]
Primary IDE Master : [Hard Disk]
Primary IDE Slave : [Hard Disk]
Secondary IDE Master : [ATAPI CDROM]
Secondary IDE Slave : [Not Detected]
Third IDE Master : [Not Detected]
Third IDE Slave : [Not Detected]
Fourth IDE Master : [Not Detected]
Fourth IDE Slave : [Not Detected]
Hard Disk Write Protect [Disabled]
IDE Detect Time Out (Sec) [35]
Select Combined Mode.
↔ Select Screen
↑↓ Select Item
+- Change Option
F1 General Help
F10 Save and Exit
ESC Exit
v02.53 (C)Copyright 1985-2002, American Megatrends, Inc.

Figure 47 Advanced Tab –> Combined Mode Operation –> S-ATA 1st Channel

15. Press the Esc key.
16. Use the Up and Down Arrow keys to highlight Floppy Configuration.

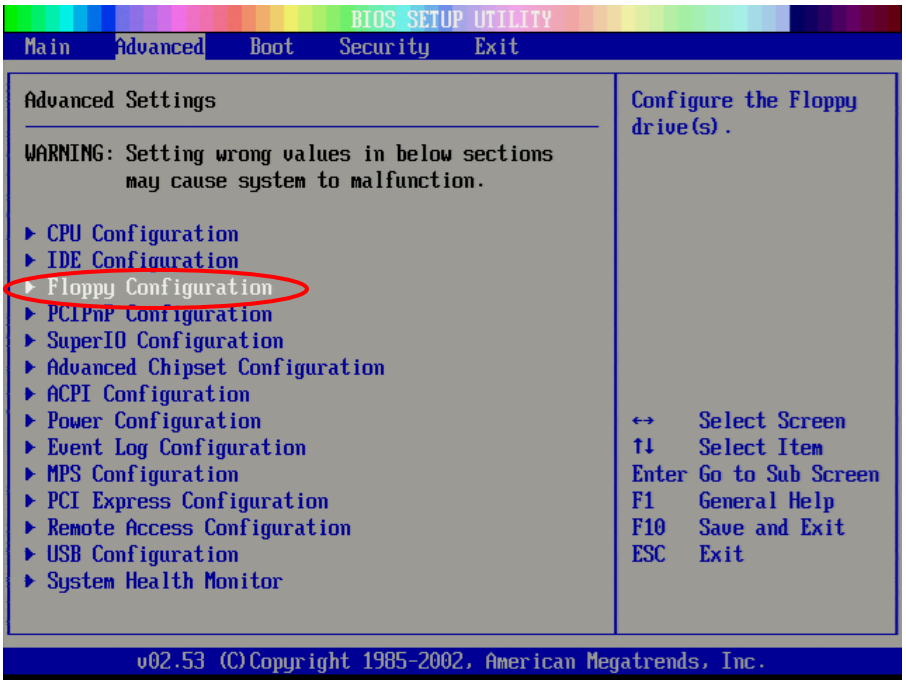


Figure 48 Advanced Tab –> Floppy Configuration

17. Press the Enter key.
18. Ensure that Floppy A is Disabled.

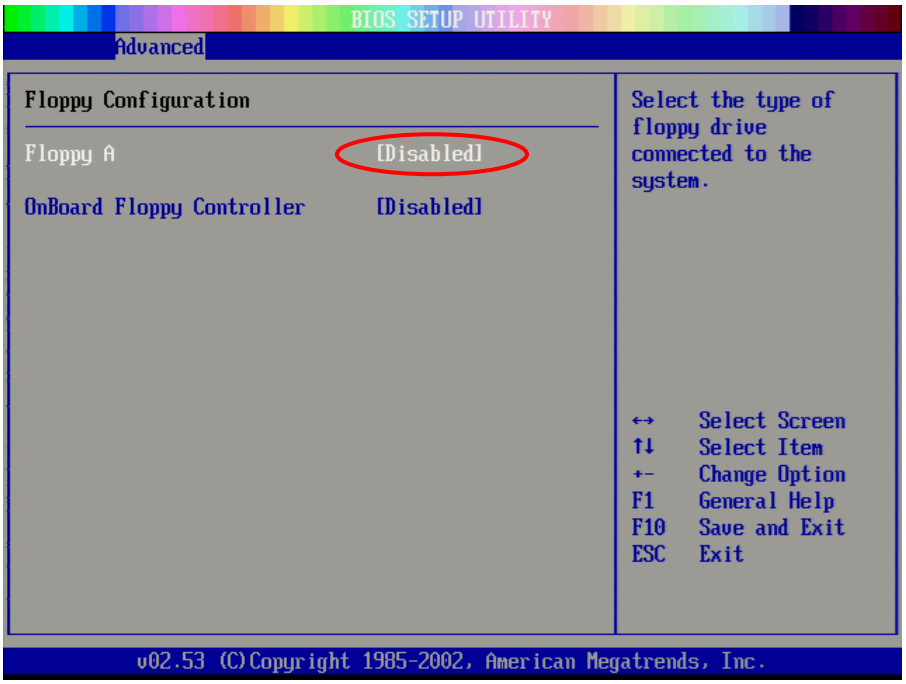


Figure 49 Advanced Tab –> Floppy A Disabled

19. Ensure that Onboard Floppy Controller is Disabled.

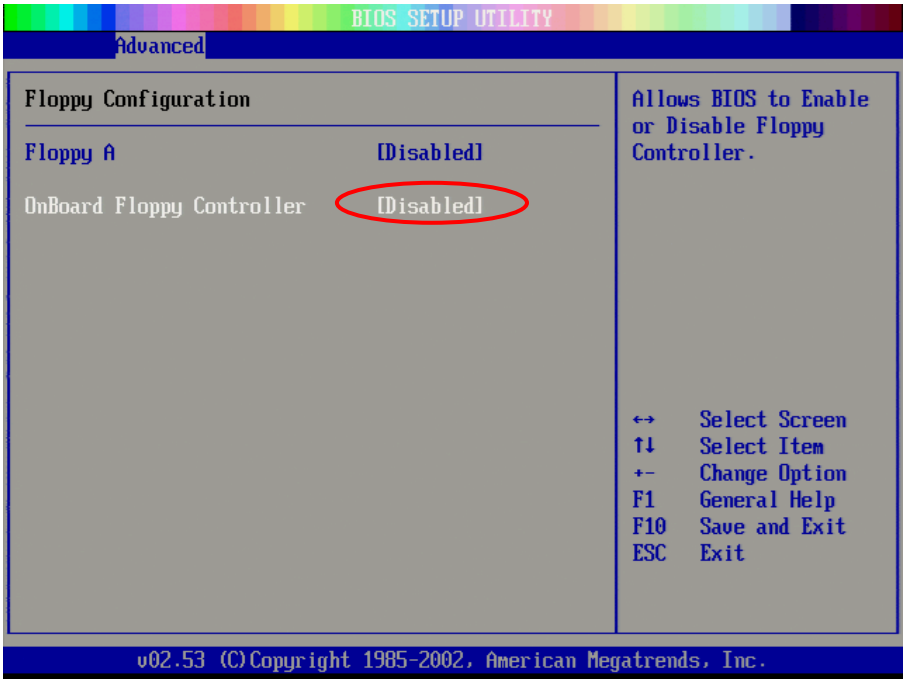


Figure 50 Advanced Tab –> Outboard Floppy Controller Disabled

20. Press the Esc key.
21. Use the Up and Down Arrow keys to highlight Power Configuration.

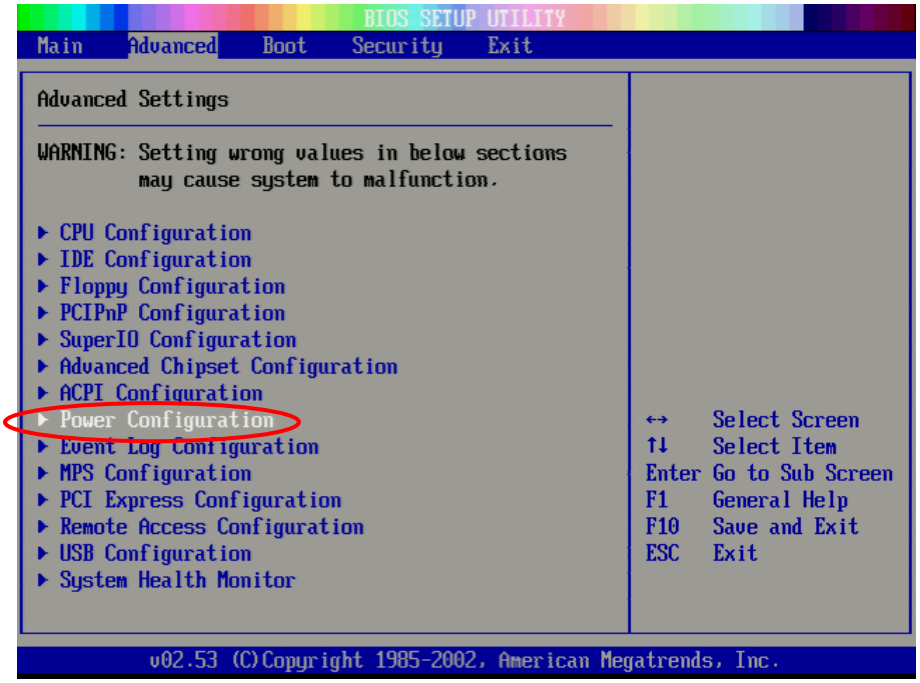


Figure 51 Advanced Tab –> Power Configuration

22. Press the Enter key.
23. Ensure that the Restore on AC Power Loss is Power Off.

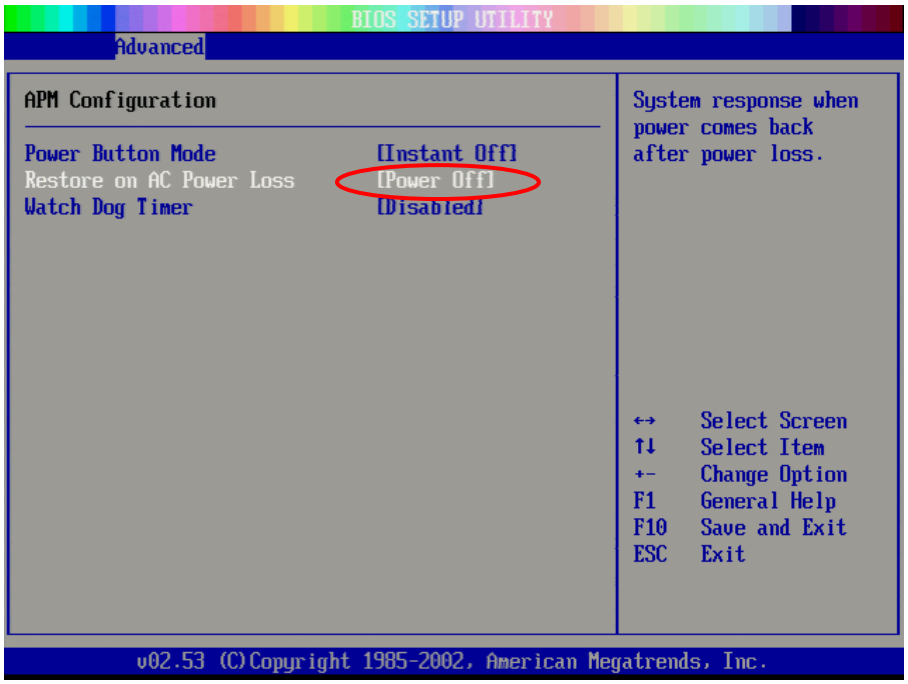


Figure 52 Advanced Tab –> Power Restore OFF

24. Press the Esc key.
25. Use the Up and Down Arrow keys to highlight MPS Configuration.

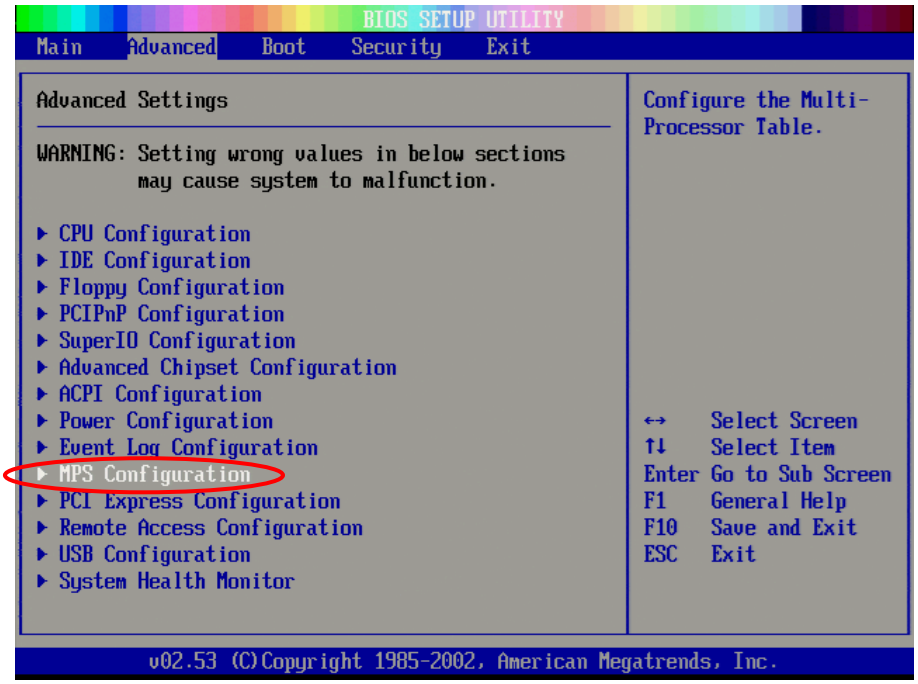


Figure 53 Advanced Tab –> MPS Configuration

26. Press the Enter key.
27. Ensure that the MPS Revision is 1.4.

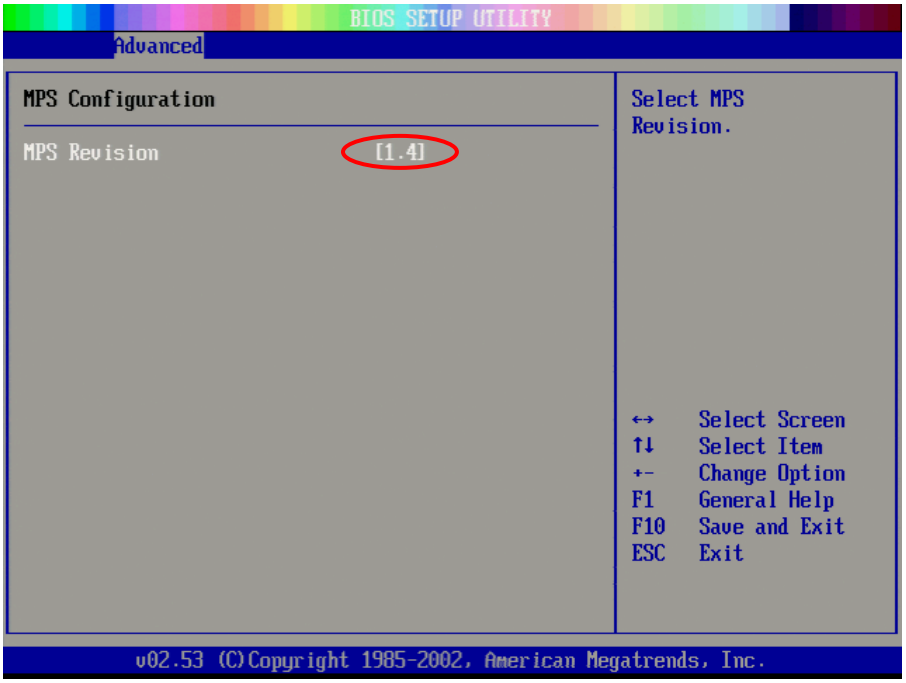


Figure 54 Advanced Tab –> Verify MPS Revision

28. Press the Esc key.
29. Press the Right Arrow key to open the Boot tab.

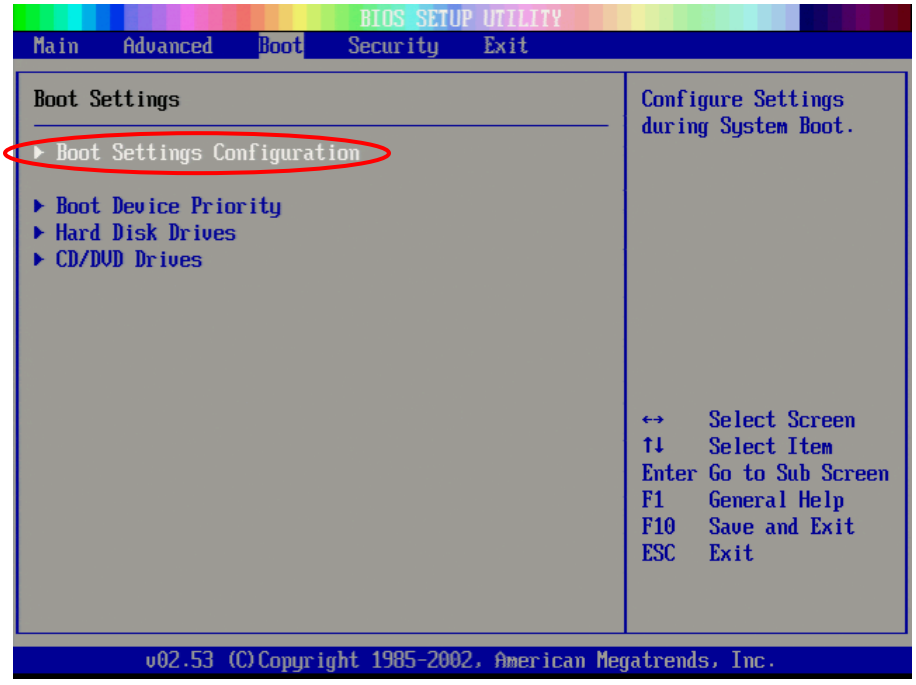


Figure 55 Boot Tab

30. Use the Up and Down Arrow keys to highlight Boot Device Priority.

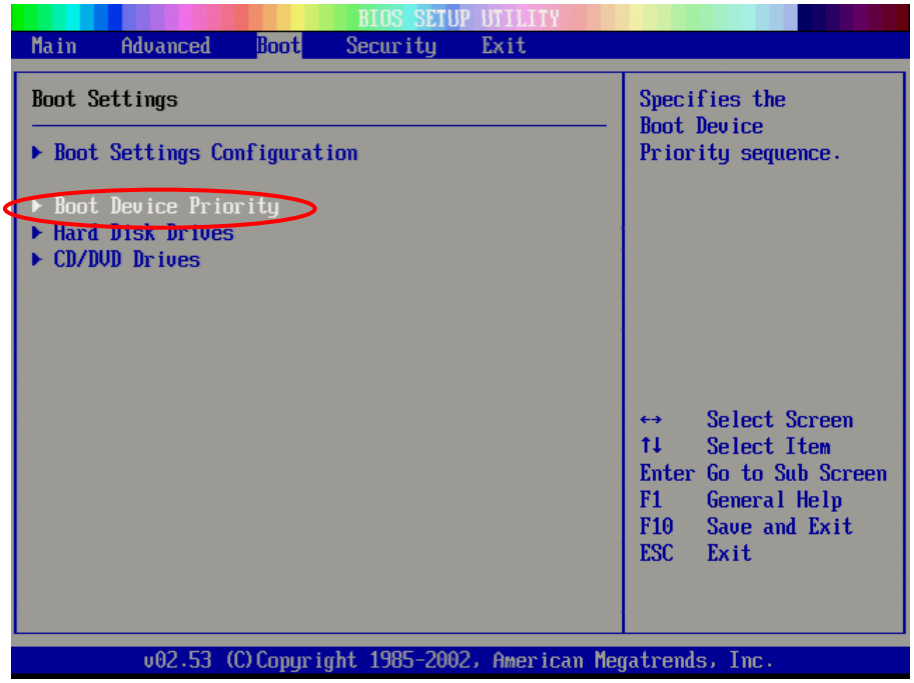


Figure 56 Boot Tab –> Boot Device Priority

31. Press the Enter key.

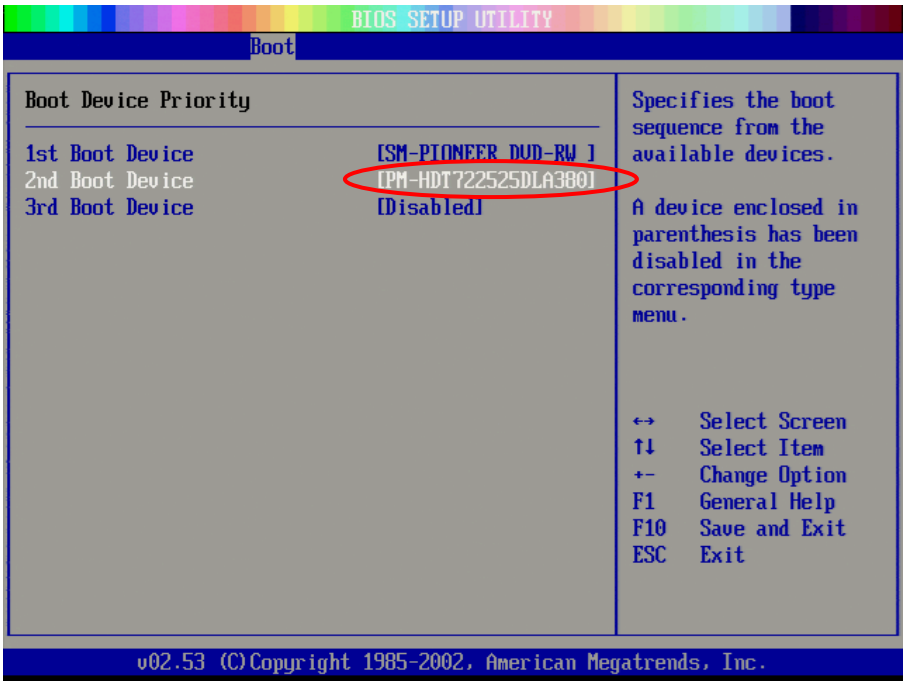

BIOS SETUP UTILITY
Boot
Boot Device Priority
1st Boot Device [SM-PIONEER DVD-RW]
2nd Boot Device [PM-HDT722525DLA380]
3rd Boot Device [Disabled]
Specifies the boot sequence from the available devices.
A device enclosed in parenthesis has been disabled in the corresponding type menu.
↔ Select Screen
↑↓ Select Item
+- Change Option
F1 General Help
F10 Save and Exit
ESC Exit
v02.53 (C)Copyright 1985-2002, American Megatrends, Inc.

Figure 57 Boot Tab –> Setting Second Boot Device

32. Ensure that the hard drive is the 2nd Boot Device.
33. Use the "-" and "+" to highlight the boot device.
34. Press enter to display the device selection options dialog.
35. Ensure that the 1st Boot Device is the DVD-RW.

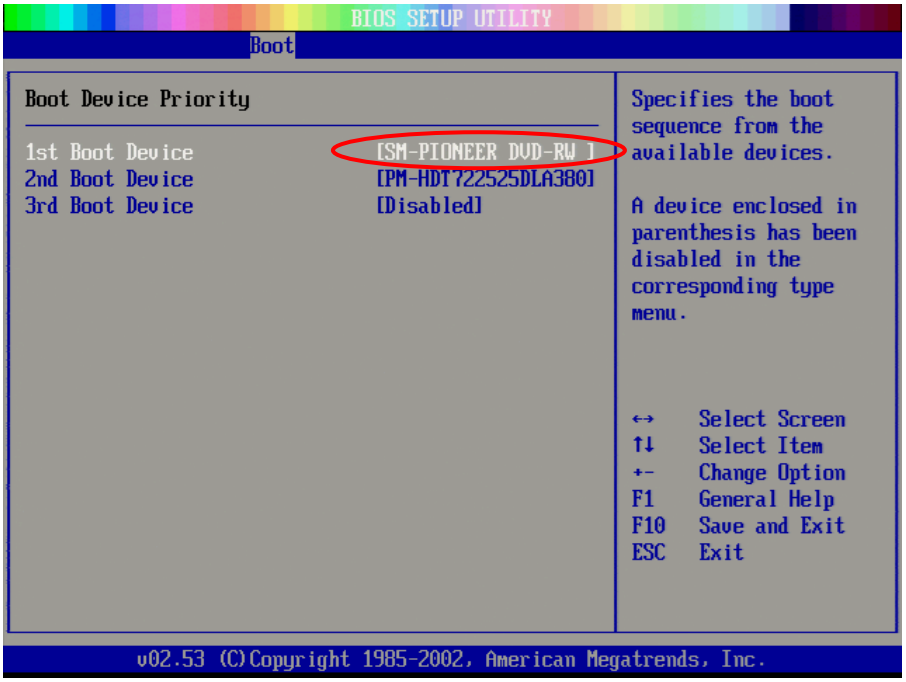

BIOS SETUP UTILITY
Boot
Boot Device Priority
1st Boot Device [SM-PIONEER DVD-RW]
2nd Boot Device [PM-HDT722525DLA380]
3rd Boot Device [Disabled]
Specifies the boot sequence from the available devices.
A device enclosed in parenthesis has been disabled in the corresponding type menu.
↔ Select Screen
↑↓ Select Item
+- Change Option
F1 General Help
F10 Save and Exit
ESC Exit
v02.53 (C)Copyright 1985-2002, American Megatrends, Inc.

Figure 58 Boot Tab –> Setting First Boot Device

36. Press the Esc key.
37. Press the Right Arrow key to open the Security tab.

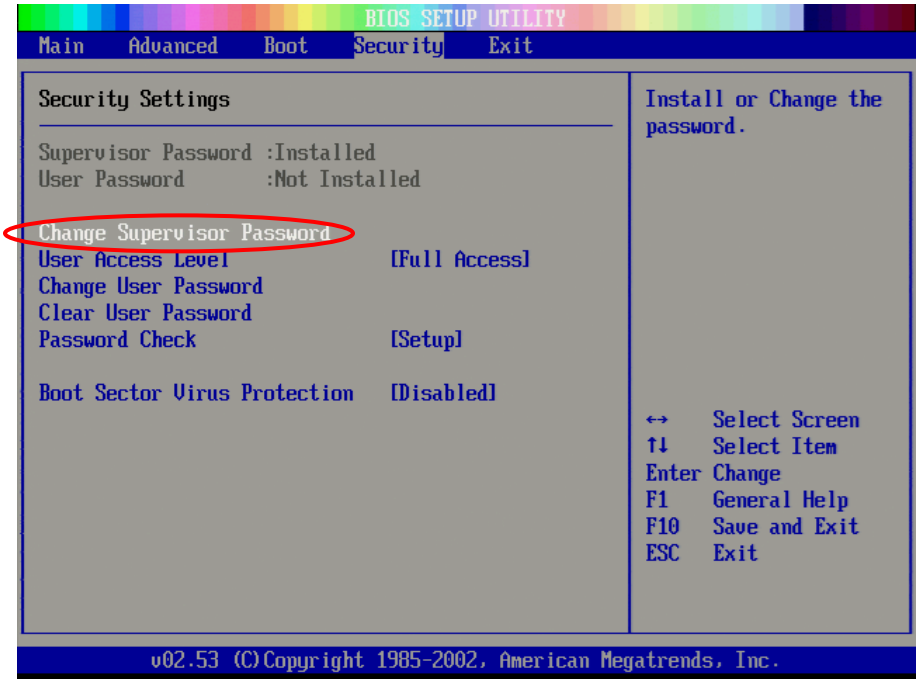


Figure 59 Security Tab

38. Use the Up and Down Arrow keys to highlight Change Supervisor Password.
39. Press the Enter key.

40. Enter **eson** in lower case.

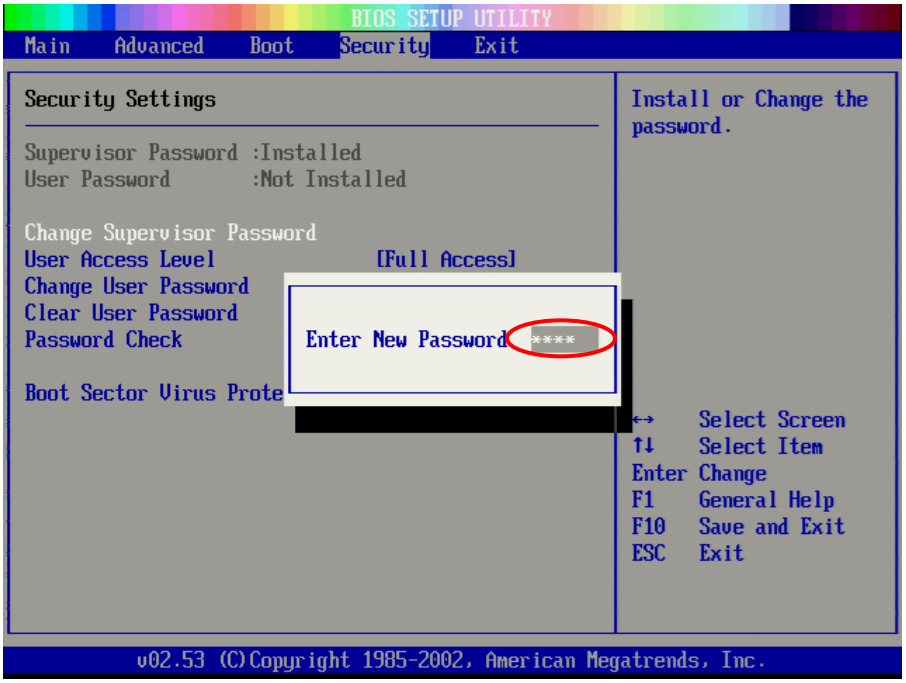


Figure 60 Security Tab –> Change Supervisor Password

41. Press Enter Key.
42. Re-enter **eson** in lower case to confirm the new password.

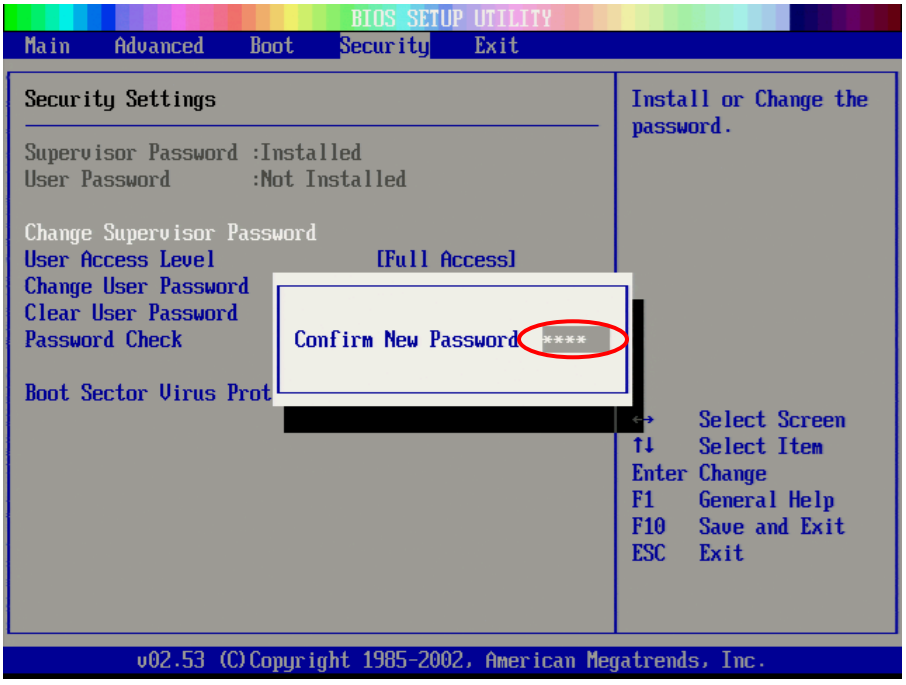


Figure 61 Security Tab –> Confirm New Password

43. Press the Enter Key.

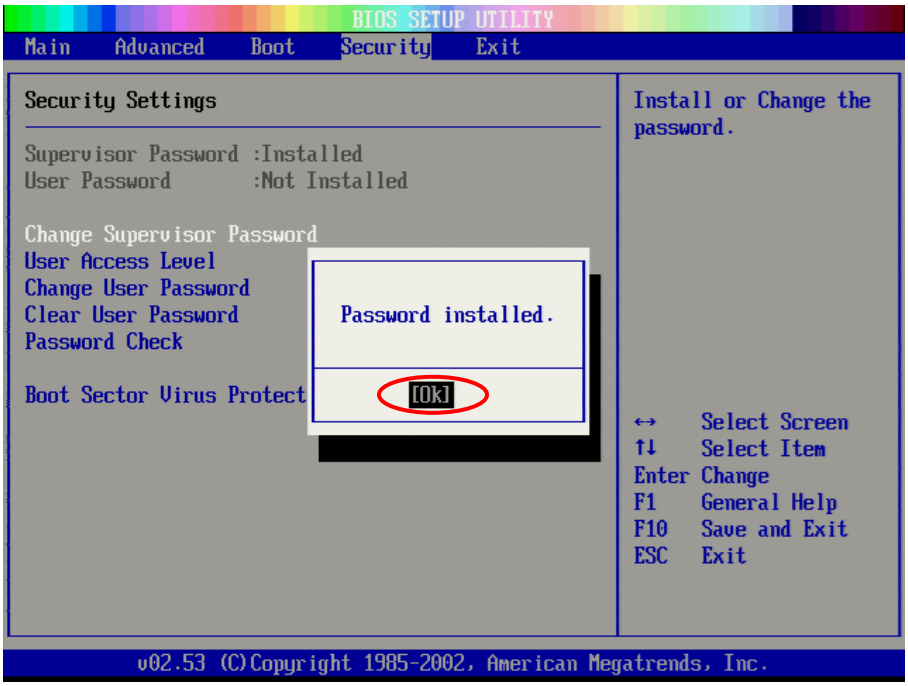


Figure 62 Security Tab –> Password Changed

44. Press Enter key.
45. Press the Right Arrow key to open the Exit tab.

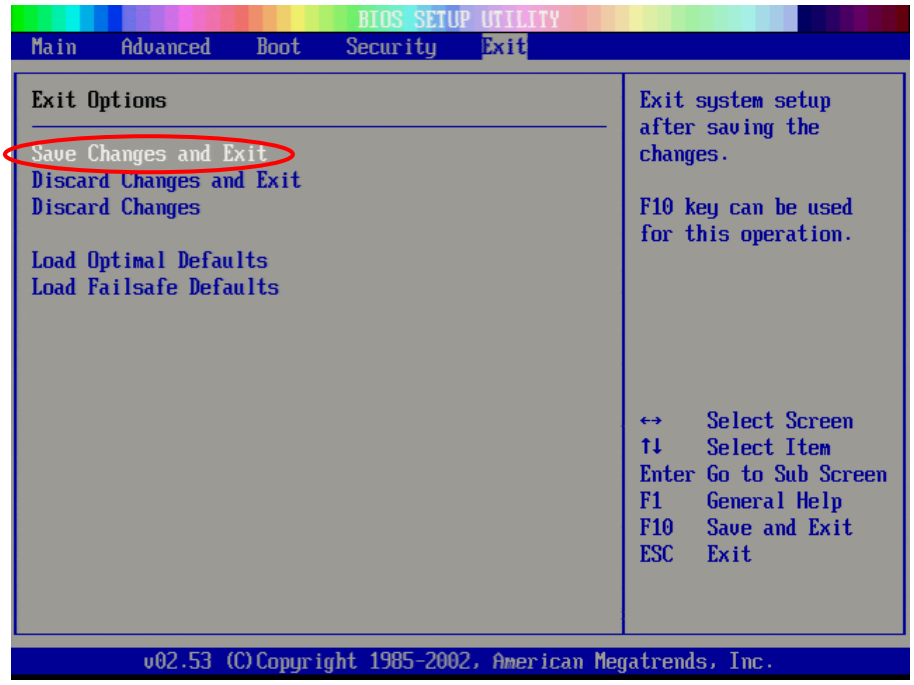


Figure 63 Exit Tab

46. Use the Up and Down Arrow keys to highlight Save Changes and Exit.
47. Press Enter Key.

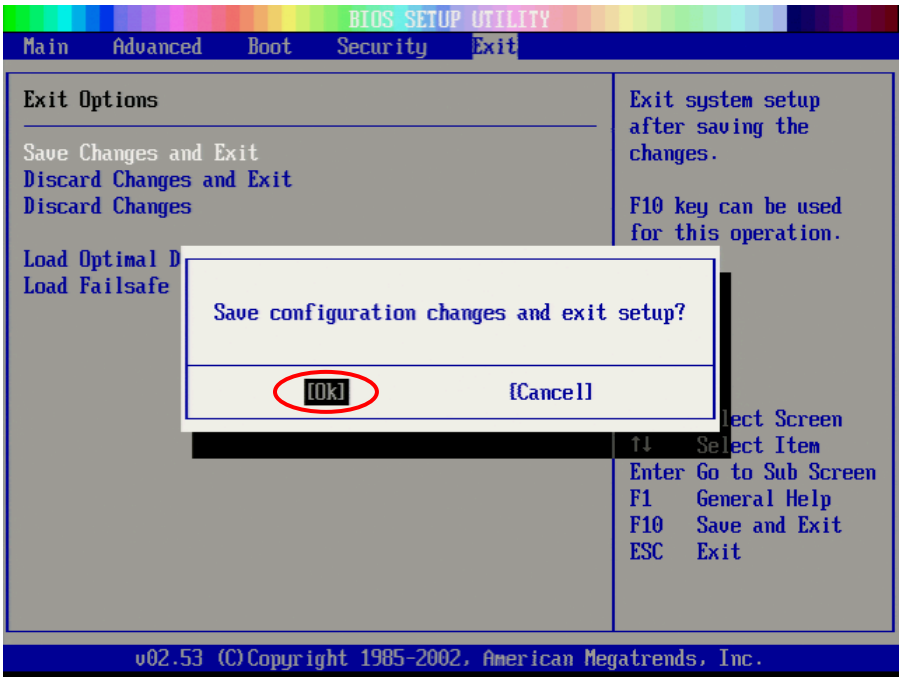


Figure 64 Exit Tab –> Saving Settings

48. Press Enter to confirm OK to Save configuration changes and exit setup.

Install/Configure Operating System

1. While the system is re-booting, open the DVD disk drive tray and insert the s5i System Disk, P/N 804255-003 CD 1 of 2.
2. Allow the system to install the Operating system with Bart PE, and it will shut itself off when complete.
3. Press the power button again and eject the OS image DVD before it begins to boot from the DVD again.
4. Allow the system to run its set up. After the system completes its setup, the system will prompt you for a password.

Figure 65 Password Prompt

5. Enter **volcano** (all lower case) for both the User name and Password.

Figure 66 Enter Username and Password

6. Select **Start** and then right click on the My Computer icon in the Start Menu.

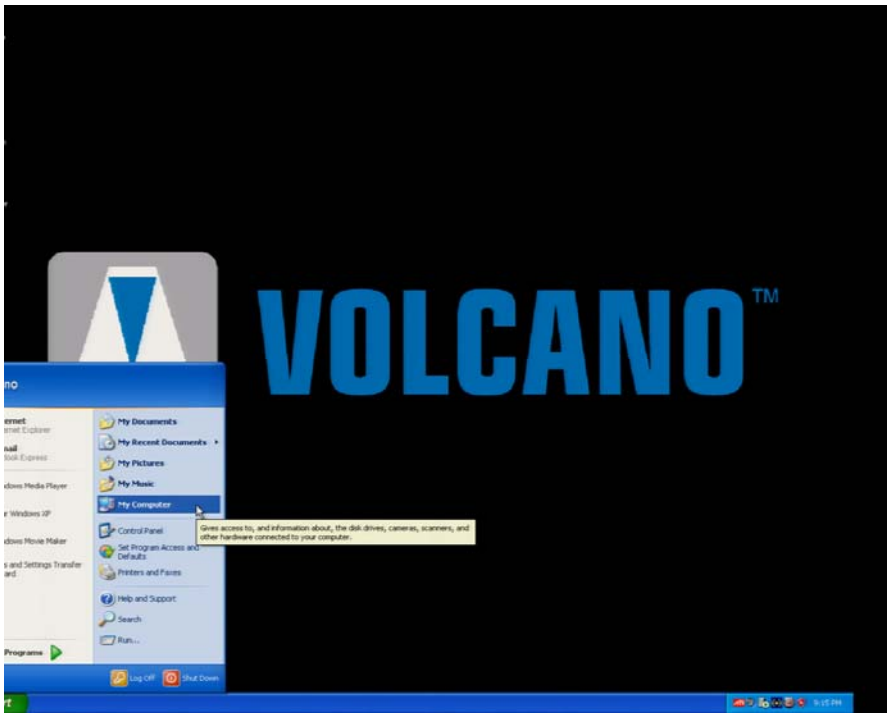


Figure 67 Select My Computer

7. Select **Properties**.

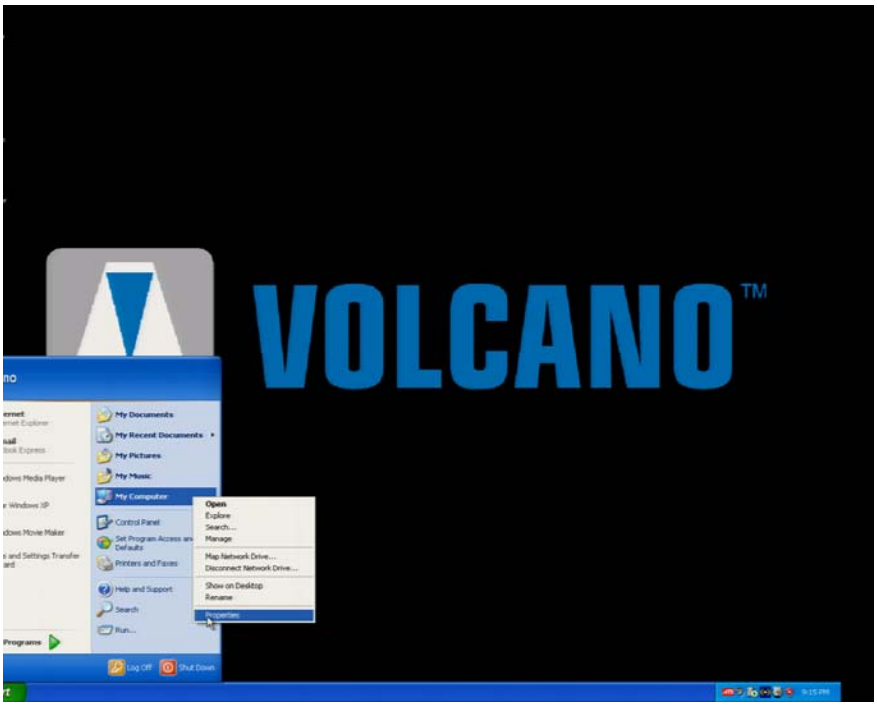


Figure 68 Select Properties

8. In the Properties menu select the Advanced tab.

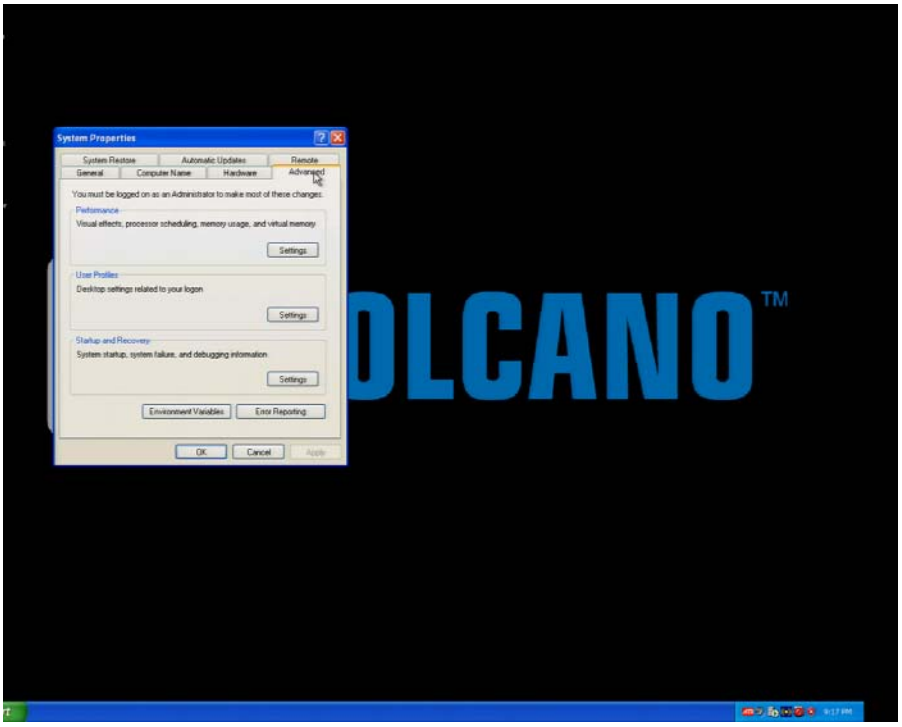


Figure 69 Select Advanced Tab

9. Click on the Settings button in the Start up and Recovery section.

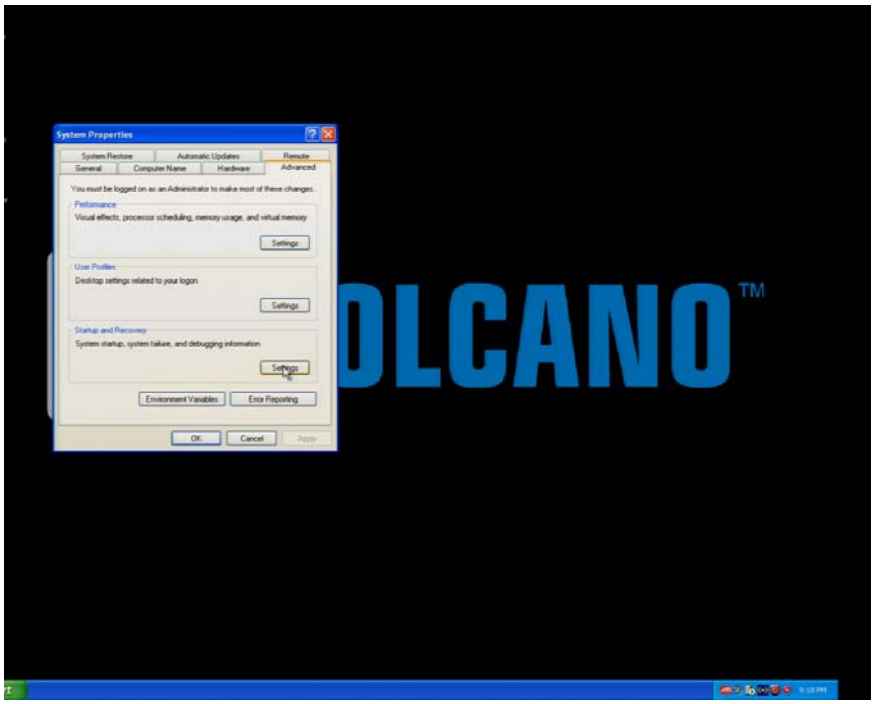


Figure 70 Start Up and Recovery Section

10. Un-check the **Time to display list of operating systems** and **Time to display recovery options when needed** (in the System Startup Section).

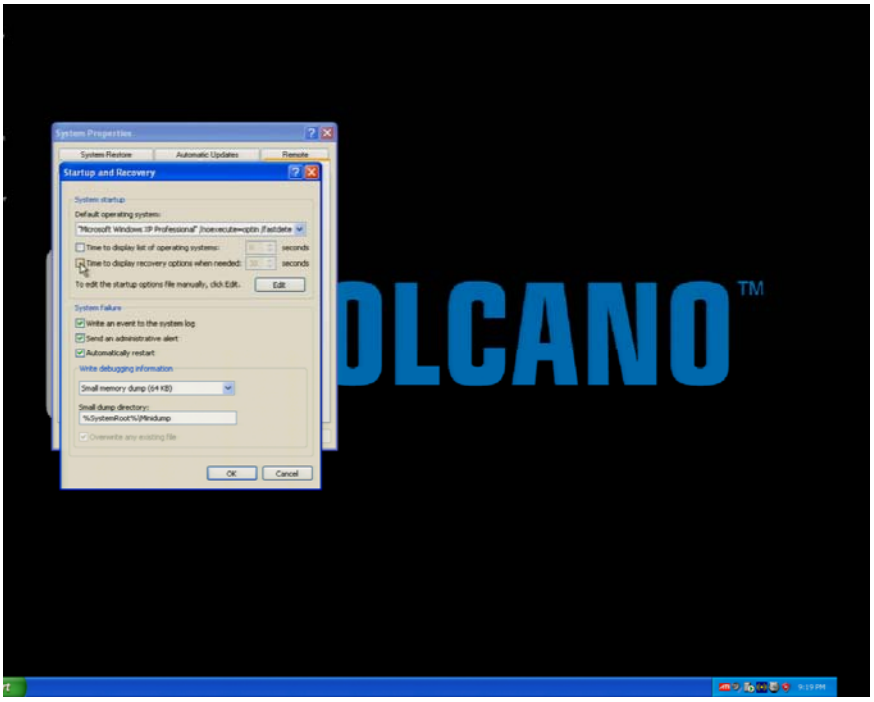


Figure 71 System Startup Section

11. Select **OK**, and then click **OK** again.
12. Select **Start** and then left click on the Control Panel icon.

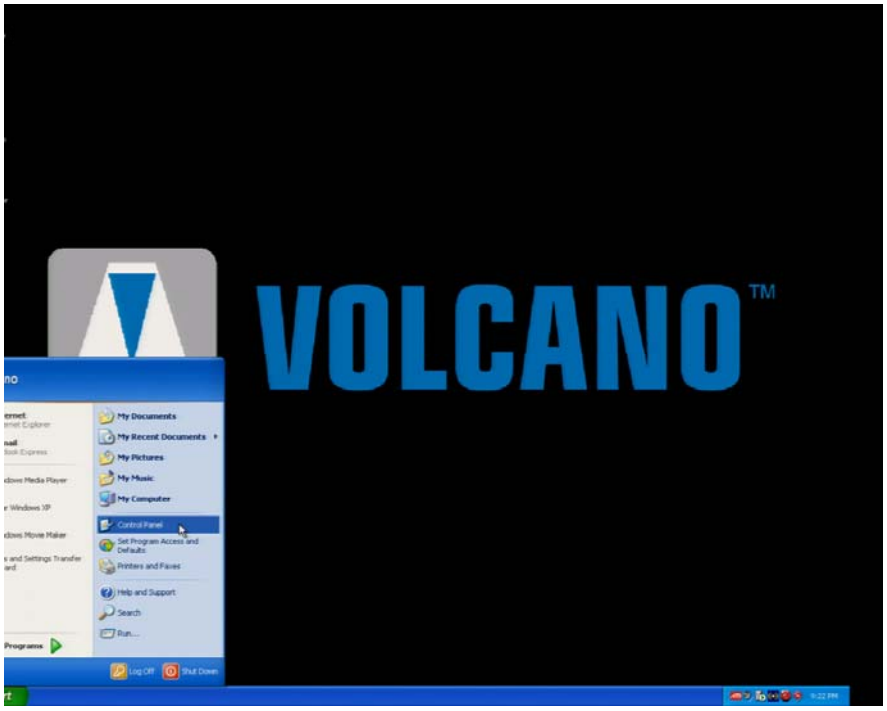


Figure 72 Select Control Panel

13. Double Click the Network Connections icon.

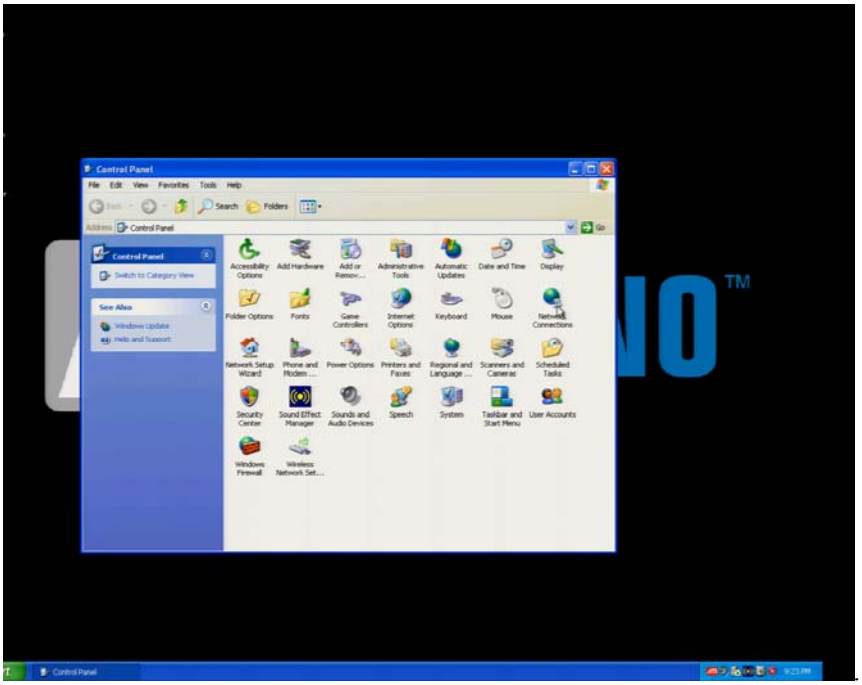


Figure 73 Network Connection

14. Right click on the Local Area Connection icon and select **Properties**.

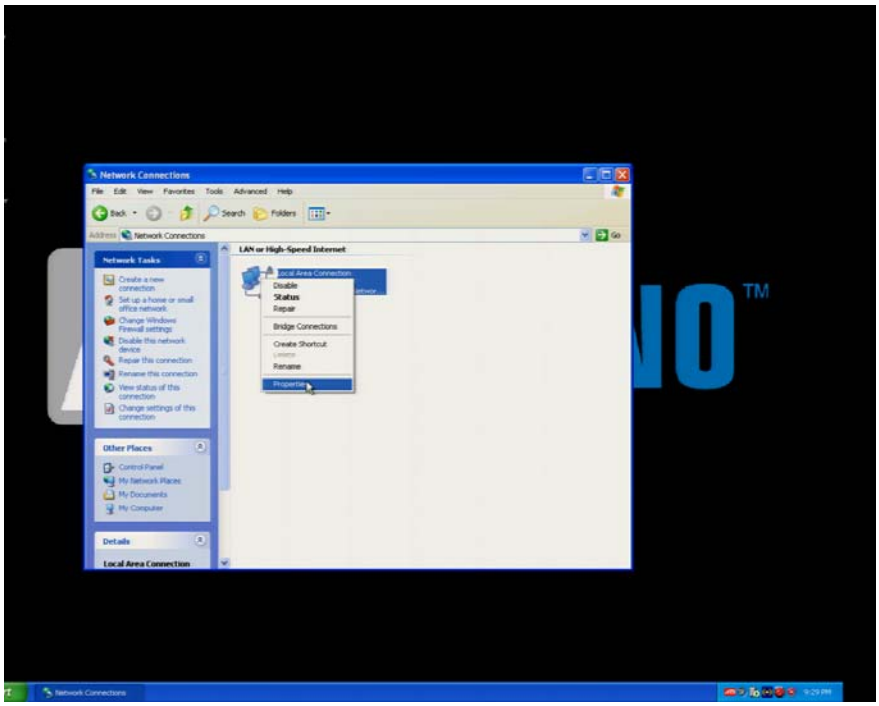


Figure 74 Local Area Connection Properties

15. Uncheck **File and Printer sharing for Microsoft Networks** and then select the OK button.

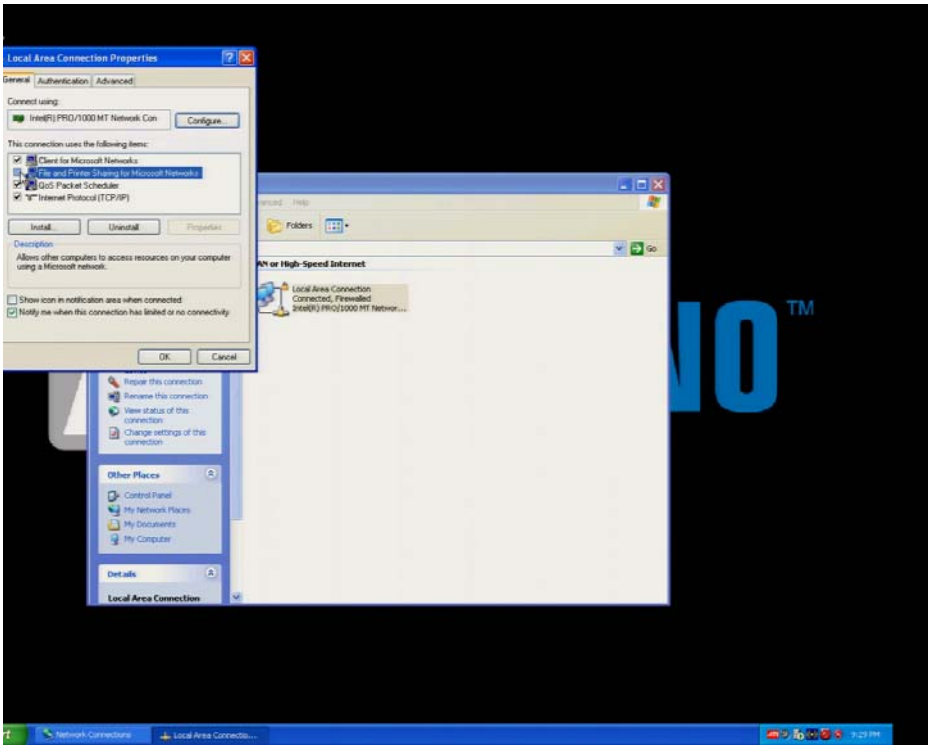


Figure 75 Disable File and Printer Sharing

16. Close the Network Connections menu.

Install/Configure the s5i Application

1. Insert the Application disk, P/N 804255-002 CD 2 of 2.
2. Select **Start** and then double click on the My Computer icon in the Start Menu.

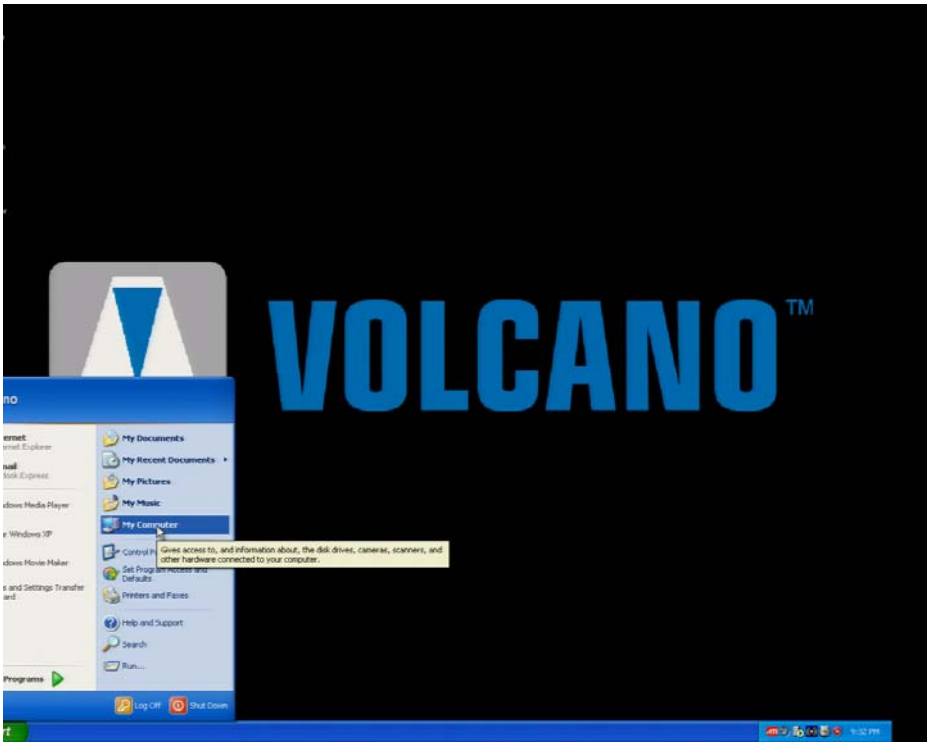


Figure 76 Select My Computer Icon

3. Double click on the DVD drive (V:).

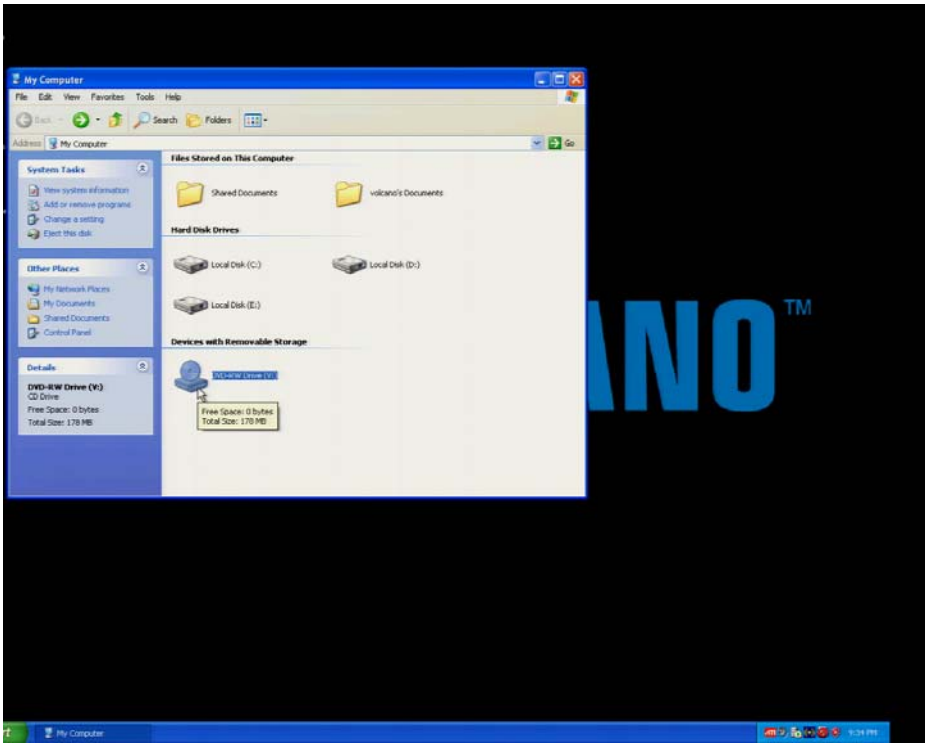


Figure 77 Double Click DVD Drive

4. Right click on the Setup.exe icon. Select **Open**.

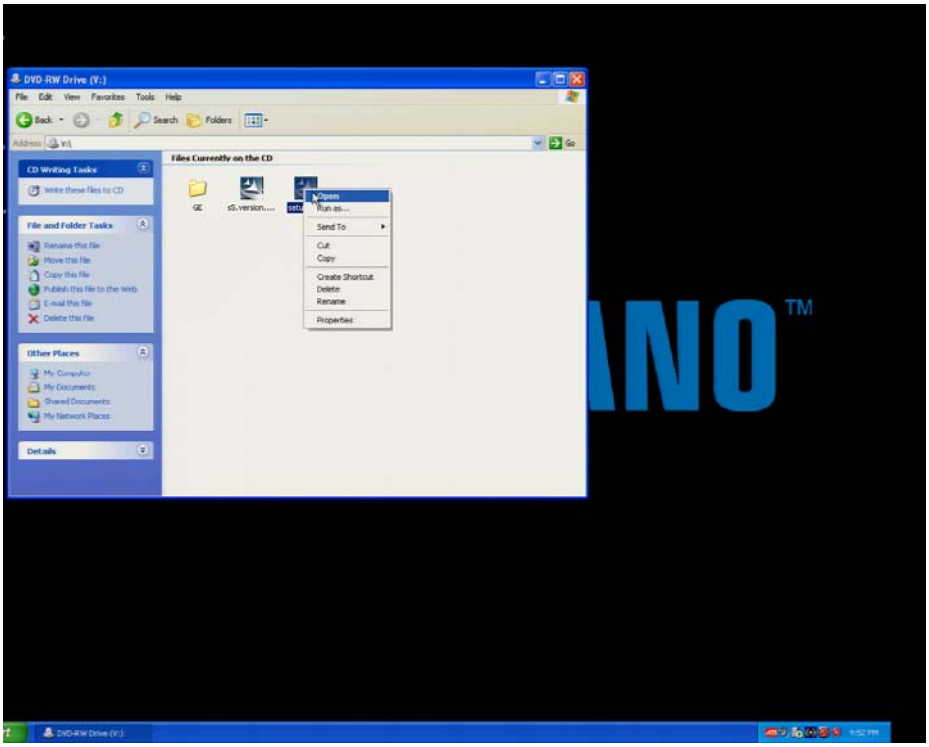


Figure 78 Open Meridian2 X.exe

5. The InstallShield Wizard will prepare the install by configuring Windows Installer.
6. At the Volcano s5i – InstallShield Wizard select the Next button.

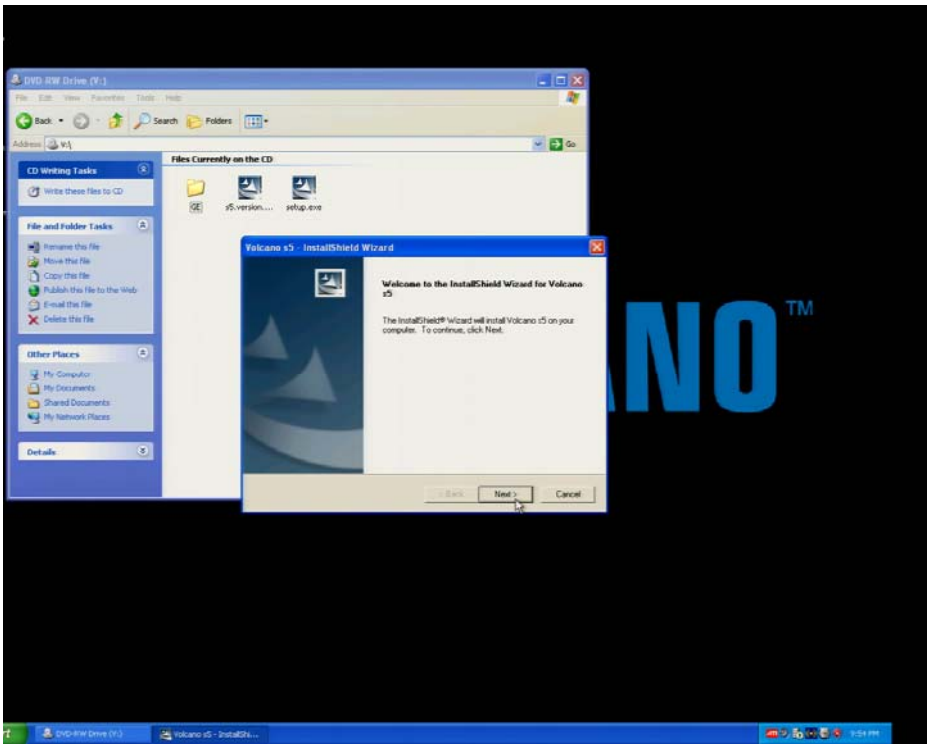

Files Currently on the CD
Volcano s5 - InstallShield Wizard
Welcome to the InstallShield Wizard for Volcano s5
Next >
Cancel

Figure 79 Starting Installation

7. Enter the system serial number for the User name.

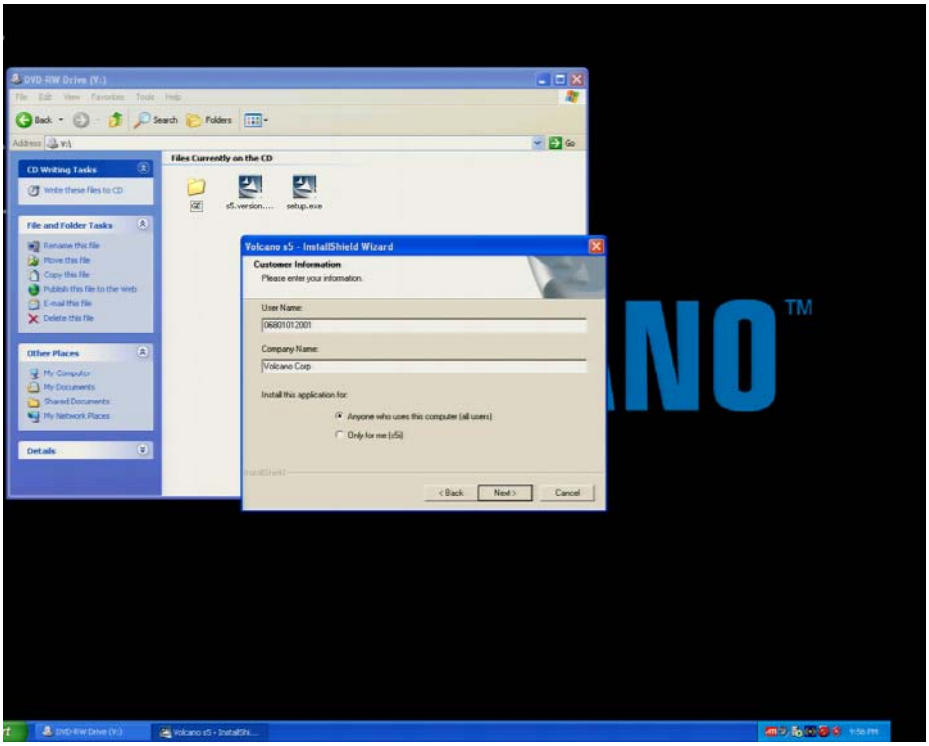


Figure 80 Enter Username and Company

8. Select **Next** then follow the on screen instructions for a typical install.

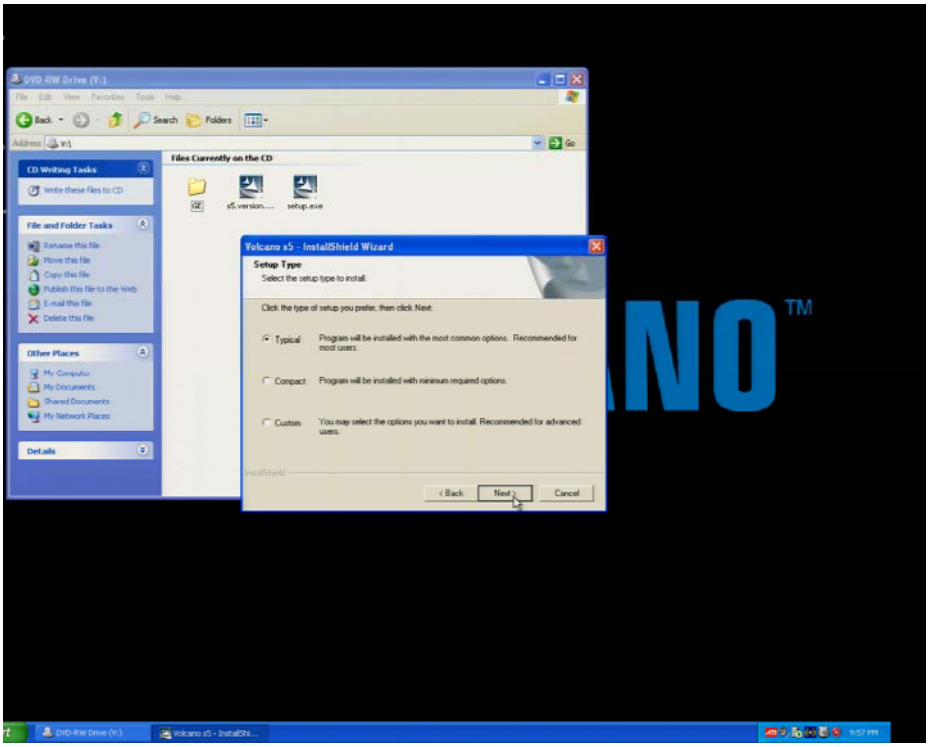

Volcano s5 - InstallShield Wizard
Setup Type
Select the setup type to install.
Click the type of setup you prefer, then click Next.
Typical
Program will be installed with the most common options. Recommended for most users.
Compact
Program will be installed with minimum required options.
Custom
You may select the options you want to install. Recommended for advanced users.
< Back
Next >
Cancel

Figure 81 Select Typical Install

9. Continue selecting the Next button, until the Finish button appears.

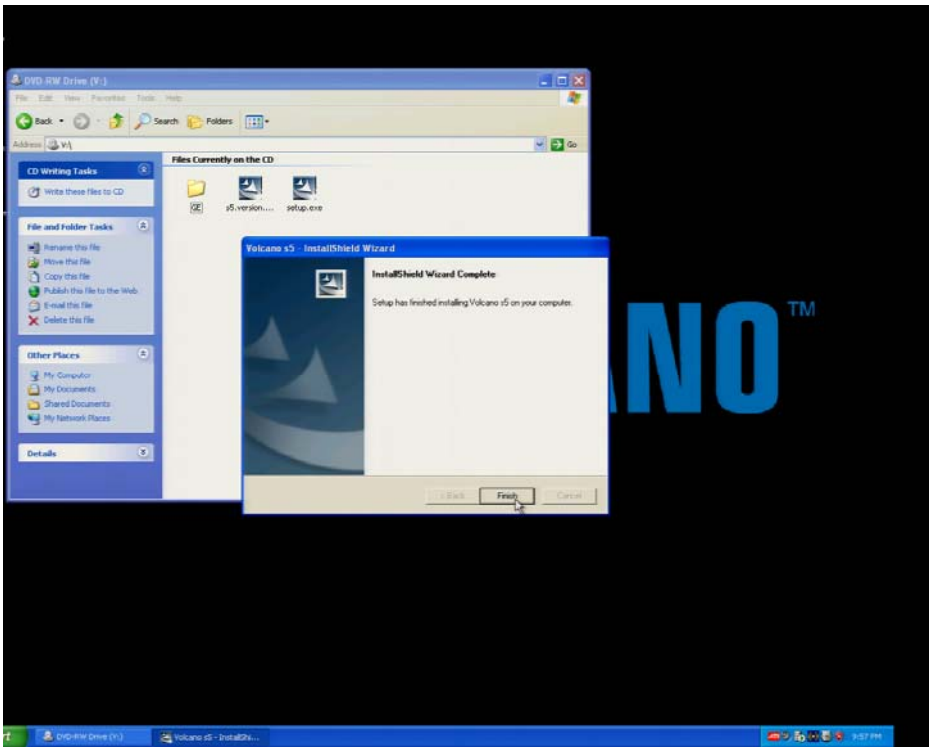

Files Currently on the CD
Volcano s5 - InstallShield Wizard
InstallShield Wizard Complete
Setup has finished installing Volcano s5 on your computer.
Finish

Figure 82 Finish Installation

10. Select the Finish button.
11. A command prompt window will open and load the DICOM and DB configurations.

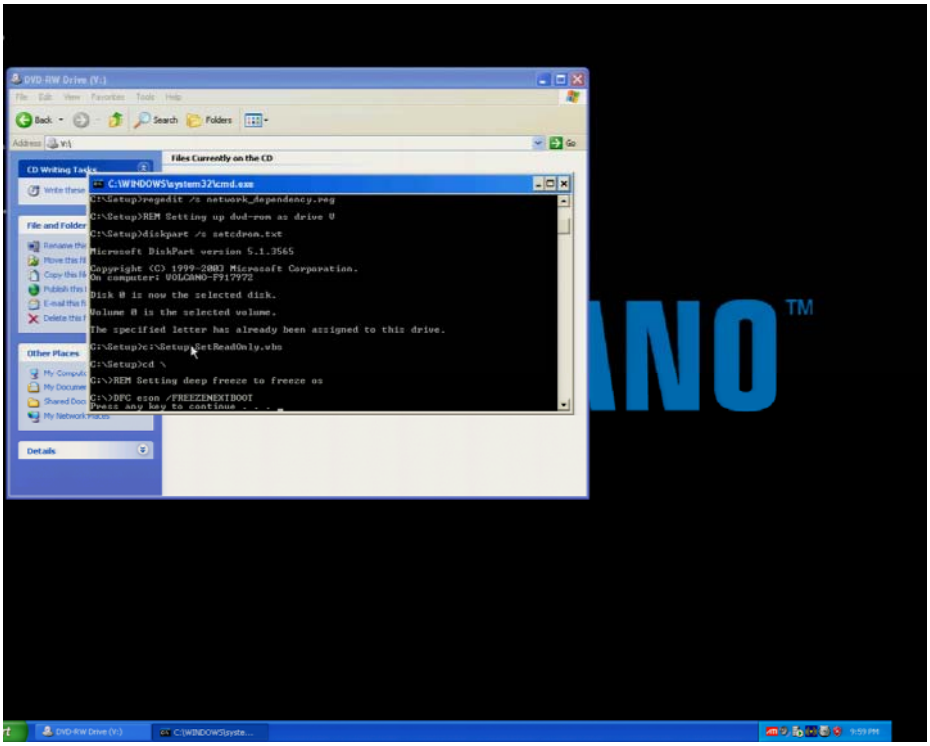

C:\WINDOWS\system32\cmd.exe
C:\Setup>regedit /s network_dependency.reg
C:\Setup>REM Setting up dvd-rom as drive U
C:\Setup>diskpart /s setcdrom.txt
Microsoft DiskPart version 5.1.3565
Copyright (C) 1999-2003 Microsoft Corporation.
On computer: VOLCANO-F917972
Disk 0 is now the selected disk.
Volume 0 is the selected volume.
The specified letter has already been assigned to this drive.
C:\Setup>cd \
C:\>REM Setting deep freeze to freeze os
C:\>DFC.exe /FREEZEMEXITBOOT
Press any key to continue . . .

Figure 83 Command Line Window

12. When loading the configuration has finished, Notepad will open to display the installation results log. Exit Notepad.

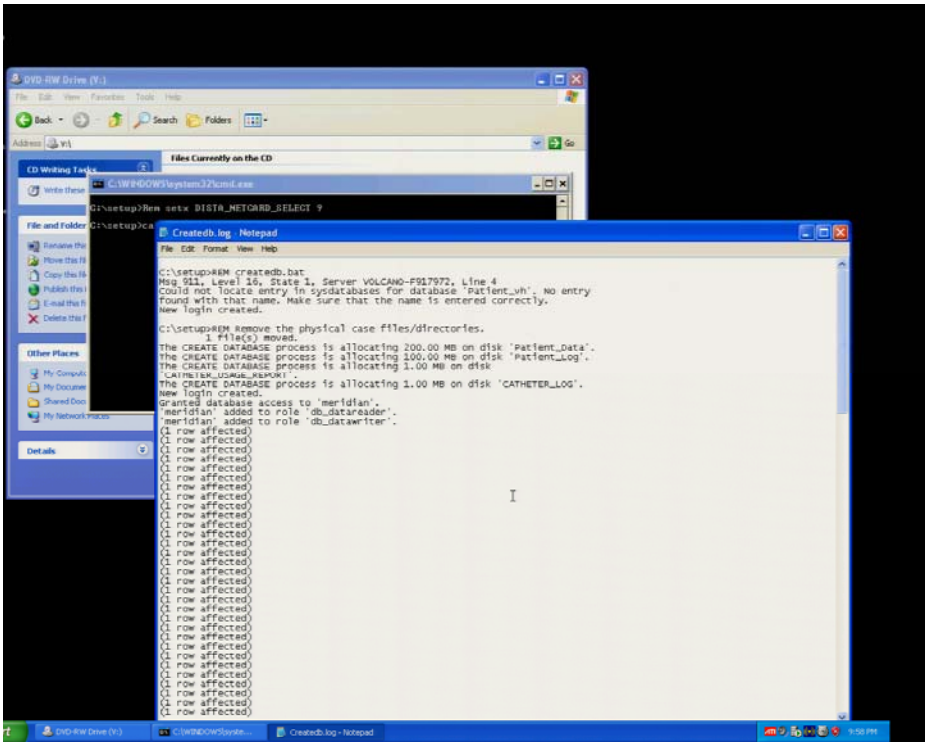

Createdb.log - Notepad
File Edit Format View Help
C:\setup>REM createdb.bat
Msg 911, Level 16, State 1, Server VOLCANO-F917972, Line 4
Could not locate entry in sysdatabases for database 'Patient_vh'. No entry
found with that name. Make sure that the name is entered correctly.
New login created.
C:\setup>REM Remove the physical case files/directories.
1 file(s) moved.
The CREATE DATABASE process is allocating 200.00 MB on disk 'Patient_Data'.
The CREATE DATABASE process is allocating 100.00 MB on disk 'Patient_Log'.
The CREATE DATABASE process is allocating 1.00 MB on disk
'CATHTELEX_USAGE_REPORT'.
The CREATE DATABASE process is allocating 1.00 MB on disk 'CATHETER_LOG'.
New login created.
Granted database access to 'meridian'.
'meridian' added to role 'db_datareader'.
'meridian' added to role 'db_datawriter'.
(1 row affected)

Figure 84 Close Notepad

13. The Command Prompt window will prompt you to **Press any key to continue**. Press any key.

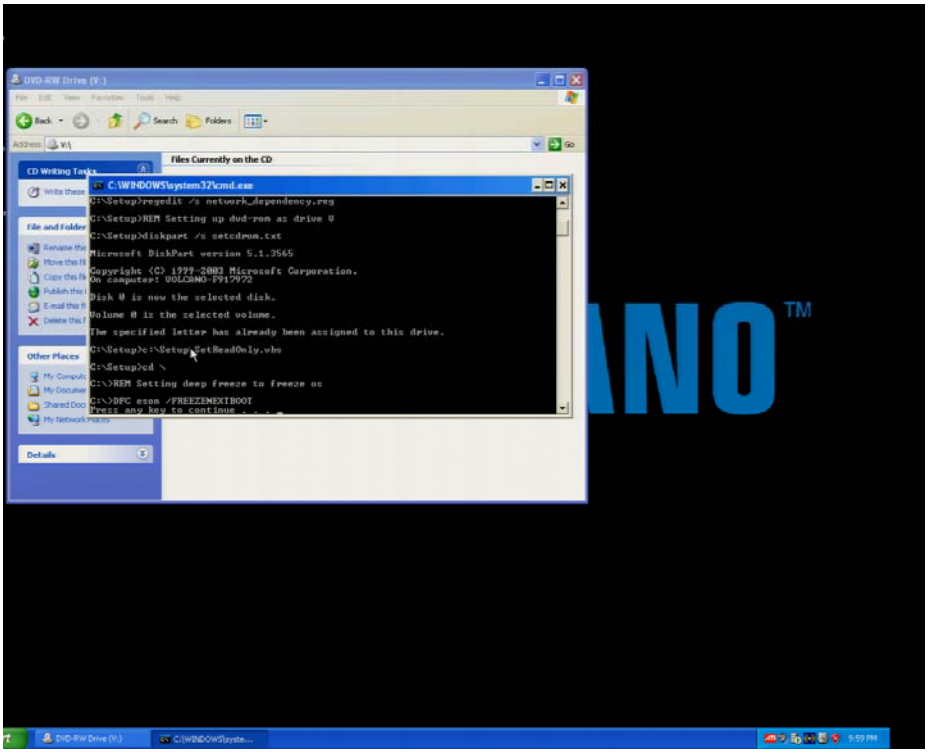

C:\WINDOWS\system32\cmd.exe
C:\Setup>regedit /s network_dependency.reg
C:\Setup>REM Setting up dvd-rom as drive V
C:\Setup>diskpart /s setcdrom.txt
Microsoft DiskPart version 5.1.3565
Copyright (C) 1999-2003 Microsoft Corporation.
On computer: VOLCANO-F917972
Disk 0 is now the selected disk.
Volume 0 is the selected volume.
The specified letter has already been assigned to this drive.
C:\Setup>c:\Setup\SetReadOnly.vbs
C:\Setup>cd \
C:\>REM Setting deep freeze to freeze os
C:\>DFC esos /FREEZENEXTBOOT
Press any key to continue . . .

Figure 85 Command Line Window

Install version 2.2.1 patch

14. The 2.2.1 patch must be installed just after loading version 2.2 application and before the system reboots. If the system reboots prior to installing version 2.2.1 patch, then DeepFreeze must be turned off in order to install the patch.
15. Select **Start** and then double click on the My Computer icon in the Start Menu.

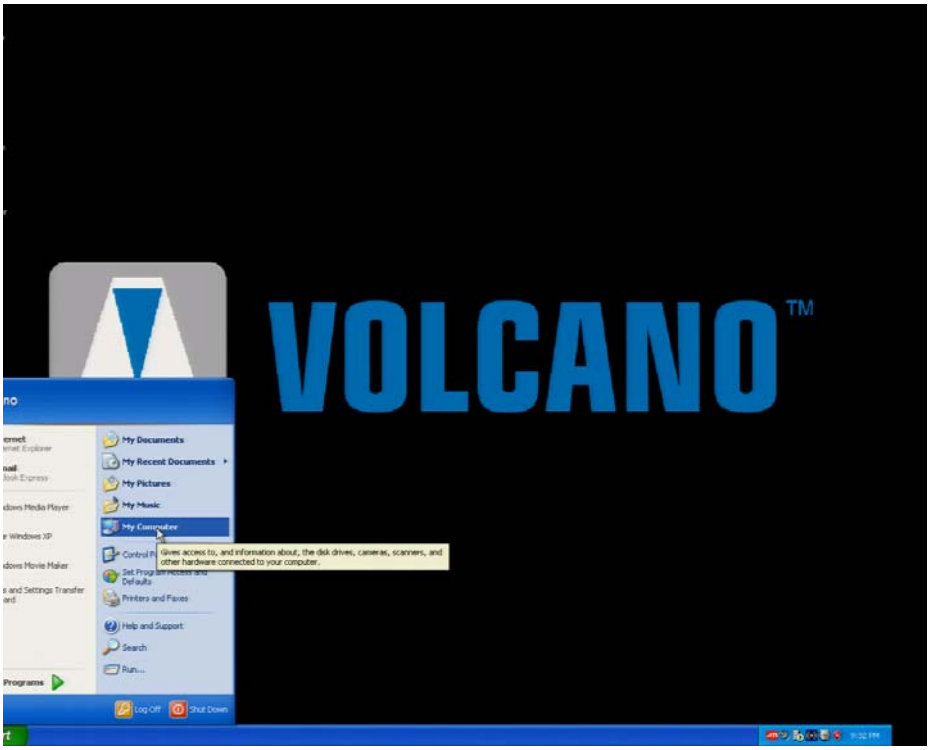


Figure 86 Select My Computer Icon

16. Double click on the DVD drive (V:).

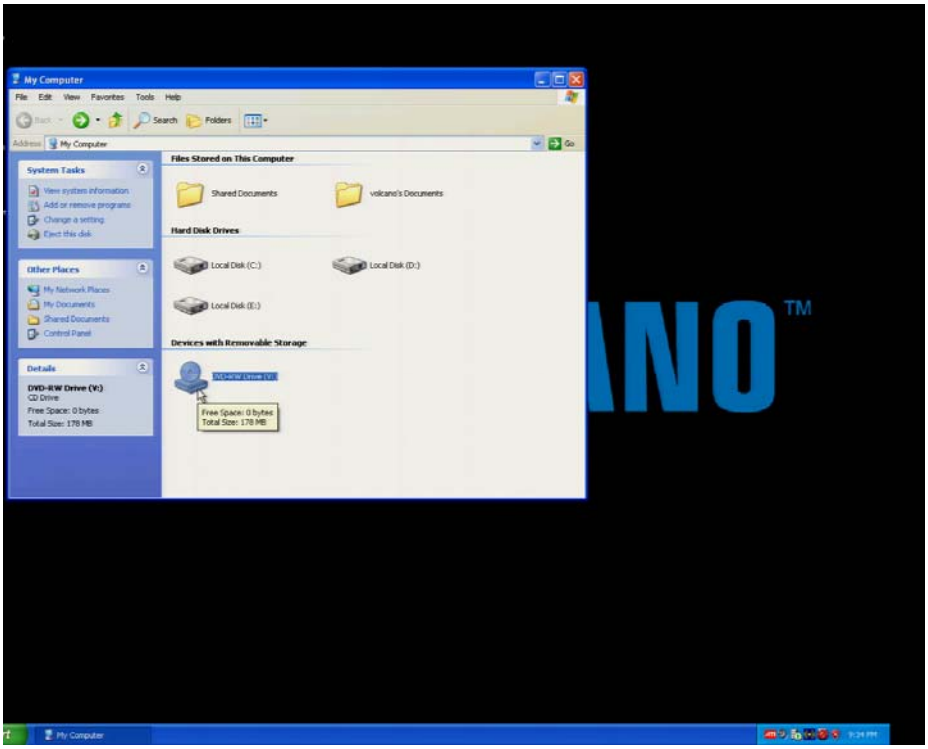


Figure 87 Double Click DVD Drive

17. Right click on the s5. version 2.2.1 patch.exe icon. Select **Open**.

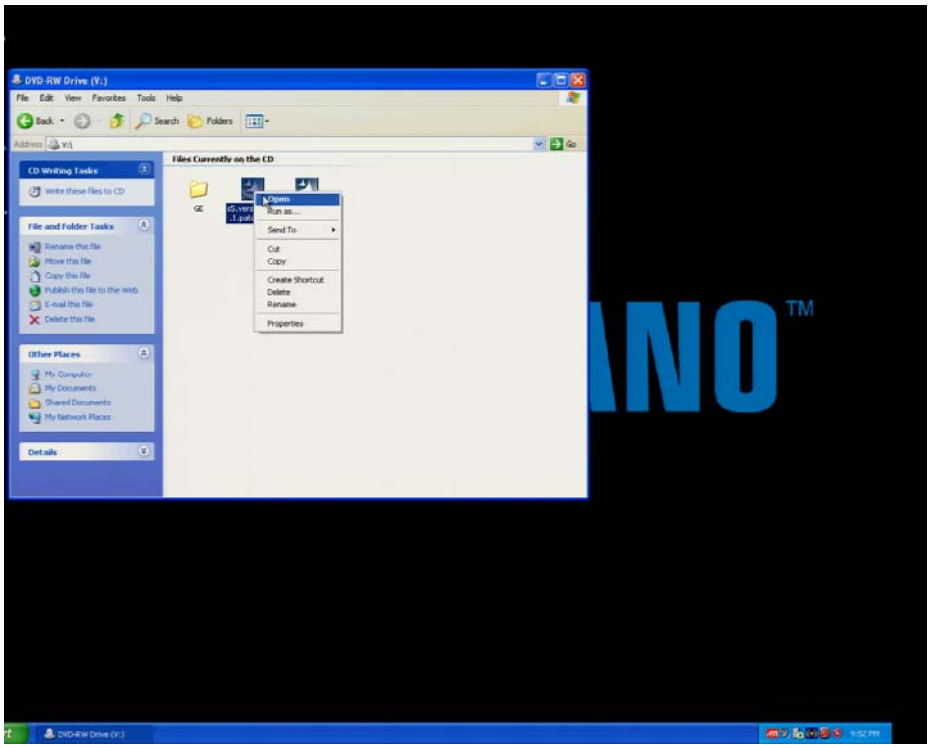


Figure 88 Open s5. version 2.2.1 patch.exe

18. The setup program will ask you to confirm that you wish to install an s5i upgrade, click yes.

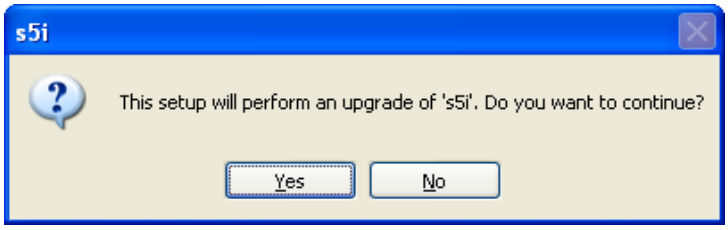


Figure 89 Confirm s5i upgrade

19. The s5i InstallShield wizard will ask you to click Next to complete the installation, click **Next.**

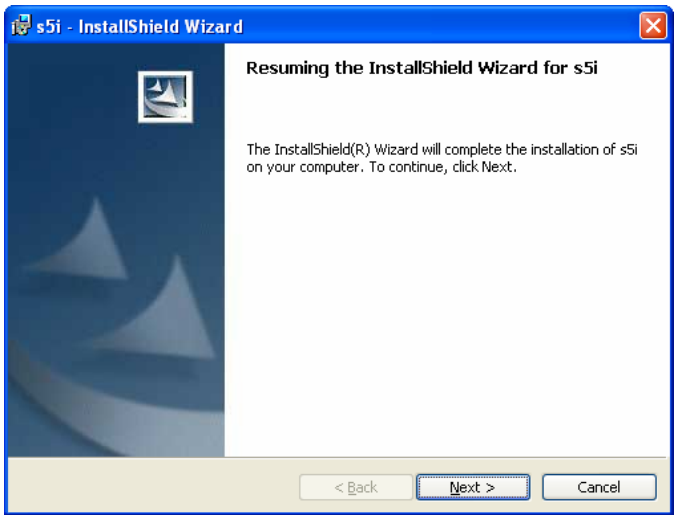

s5i - InstallShield Wizard
Resuming the InstallShield Wizard for s5i
The InstallShield(R) Wizard will complete the installation of s5i on your computer. To continue, click Next.
< Back
Next >
Cancel

Figure 90 Completing the Installation

20. The s5i InstallShield Wizard will inform you that the installation is successful and ask you to click Finish to exit the Wizard, Click **Finish.**

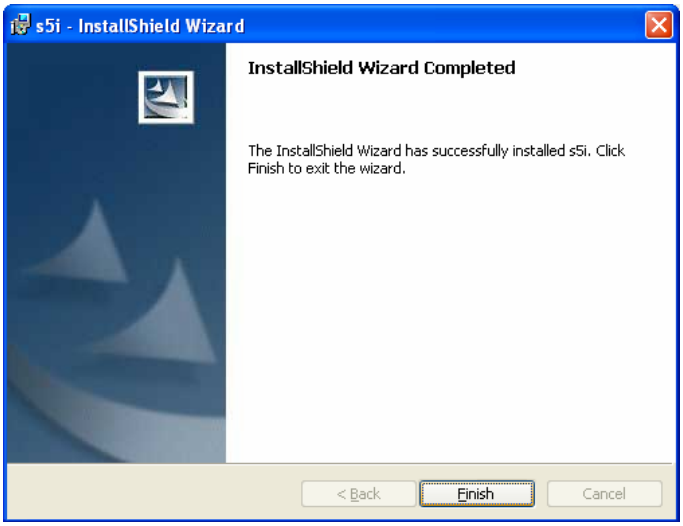

s5i - InstallShield Wizard
InstallShield Wizard Completed
The InstallShield Wizard has successfully installed s5i. Click Finish to exit the wizard.
< Back
Finish
Cancel

Figure 91 Installation complete

21. Restart the system.
22. After the system has finished rebooting, you will be prompted to enter the serial number of the system, the serial number of the Digital card and the revision number of the Digital card that was previously recorded on the Capture System Settings Appendix F saved to local (non s5i) hard drive.

Figure 92 Enter Information

23. After entering the information, select Apply.
24. The System will execute a PIM Calibration routine during the first initialization.
25. After the system completes its initialization, logon as to the Field Service Menurestart the system.

Restore Boot Order

1. Hit the Delete (Del) key when the Supermicro boot screen appears.

Figure 93 Supermicro Boot Screen

2. If you are prompted for a password, enter **eson**.
3. Use the Up and Down Arrow keys to highlight **Boot Device Priority**.

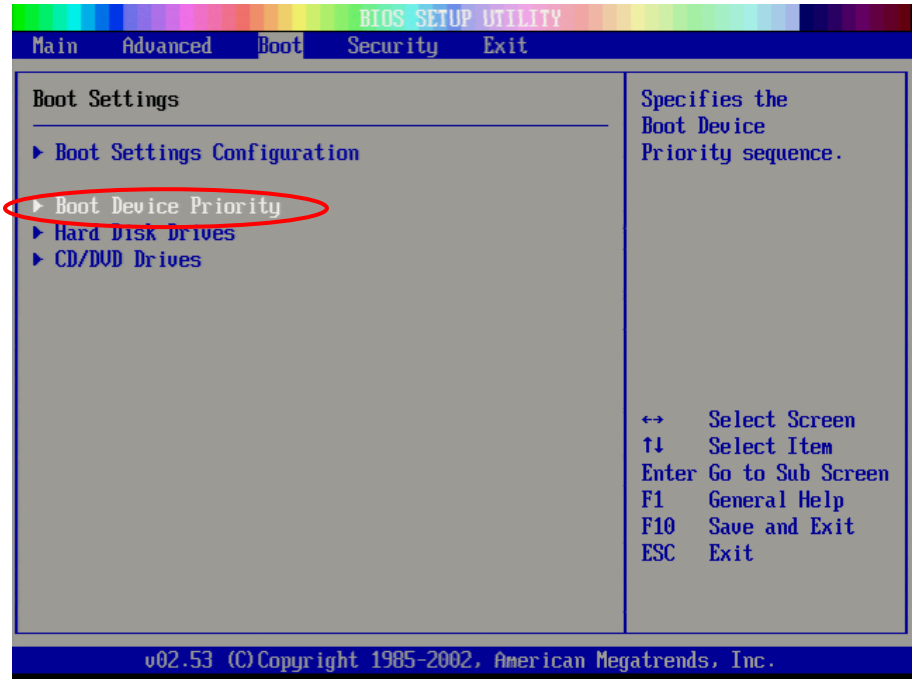


Figure 94 Boot Device Priority

4. Press the Enter key.

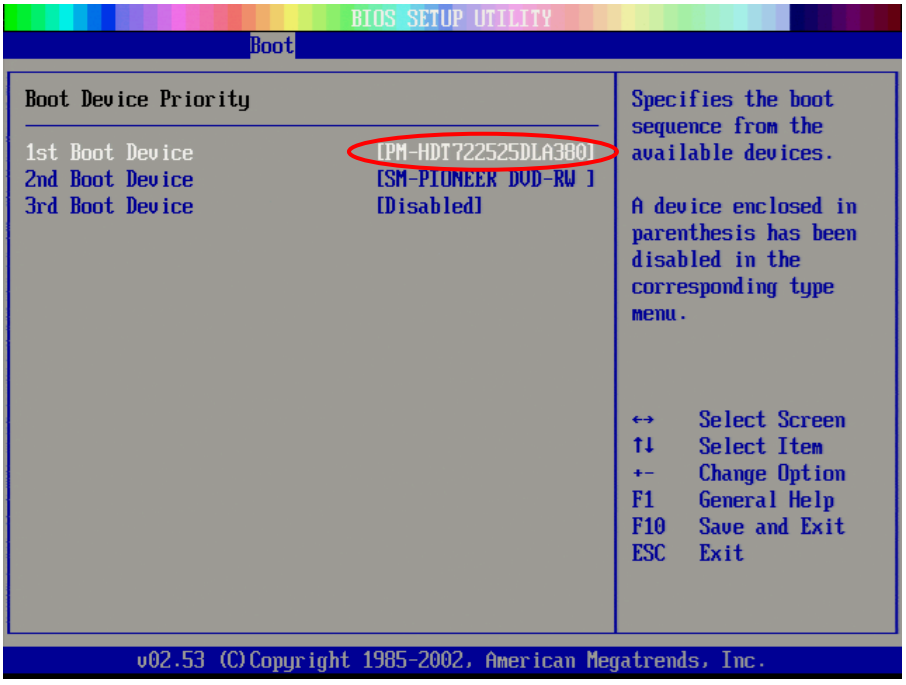

BIOS SETUP UTILITY
Boot
Boot Device Priority
1st Boot Device [PM-HDT722525DLA380]
2nd Boot Device [SM-PIONEER DVD-RW]
3rd Boot Device [Disabled]
Specifies the boot sequence from the available devices.
A device enclosed in parenthesis has been disabled in the corresponding type menu.
↔ Select Screen
↑↓ Select Item
+- Change Option
F1 General Help
F10 Save and Exit
ESC Exit
v02.53 (C)Copyright 1985-2002, American Megatrends, Inc.

Figure 95 Set First Boot Device

5. Ensure that the hard drive is the 1st Boot Device.
6. Use the "-" and "+" to highlight the boot device.
7. Press **enter** to display the device selection options dialog.
8. Ensure that the 2nd Boot Device is the DVD-RW.

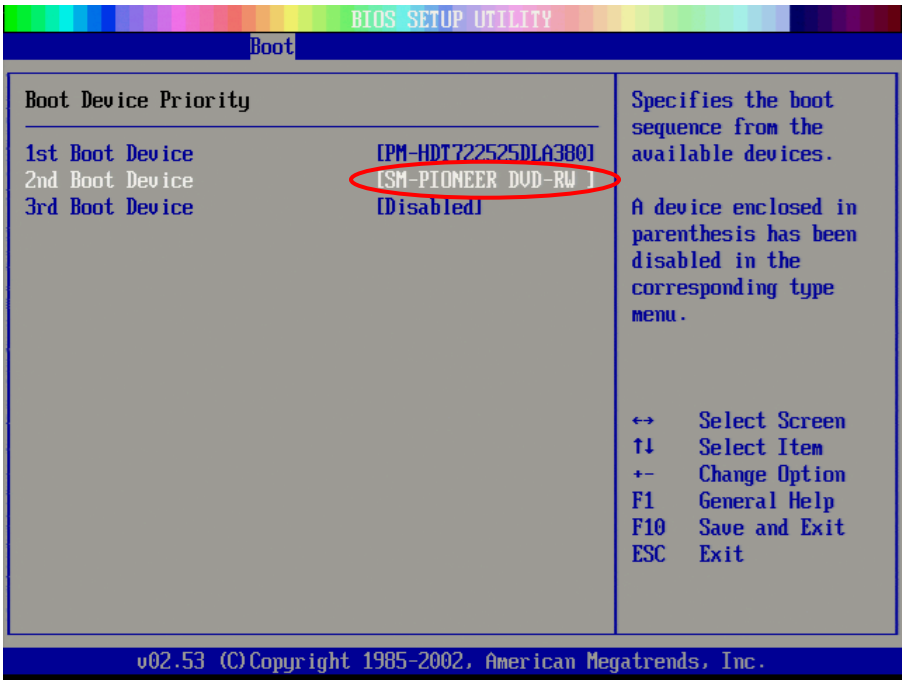

BIOS SETUP UTILITY
Boot
Boot Device Priority
1st Boot Device [PM-HDT722525DLA380]
2nd Boot Device [SM-PIONEER DVD-RW]
3rd Boot Device [Disabled]
Specifies the boot sequence from the available devices.
A device enclosed in parenthesis has been disabled in the corresponding type menu.
↔ Select Screen
↑↓ Select Item
+- Change Option
F1 General Help
F10 Save and Exit
ESC Exit
v02.53 (C)Copyright 1985-2002, American Megatrends, Inc.

Figure 96 Set Second Boot Device

9. Press the Esc key.
10. Press the Right Arrow key to open the Exit tab.

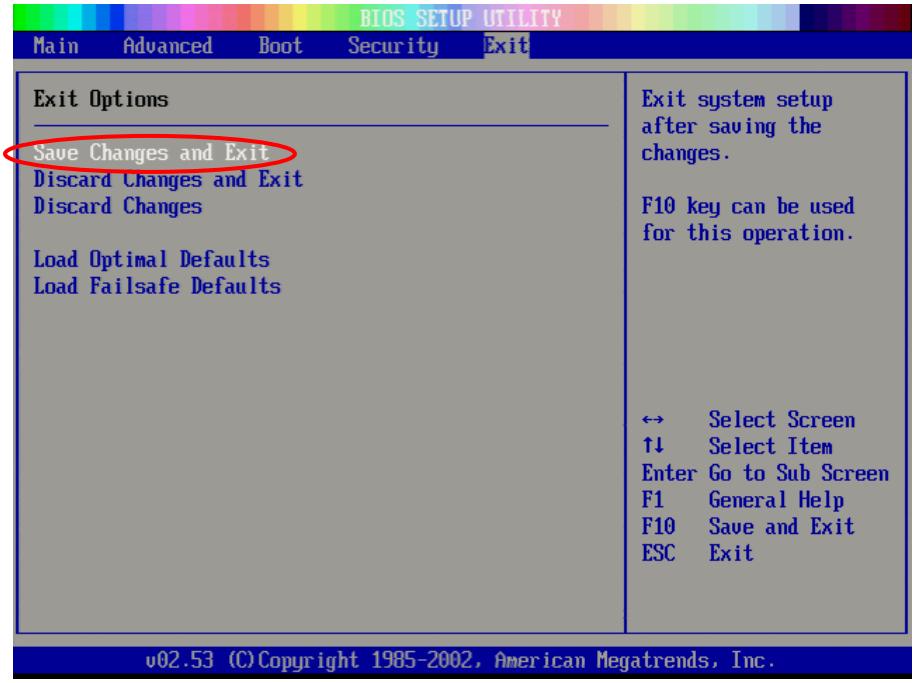


Figure 97 Save Changes

11. Use the Up and Down Arrow keys to highlight Save Changes and Exit.
12. Press the Enter Key.

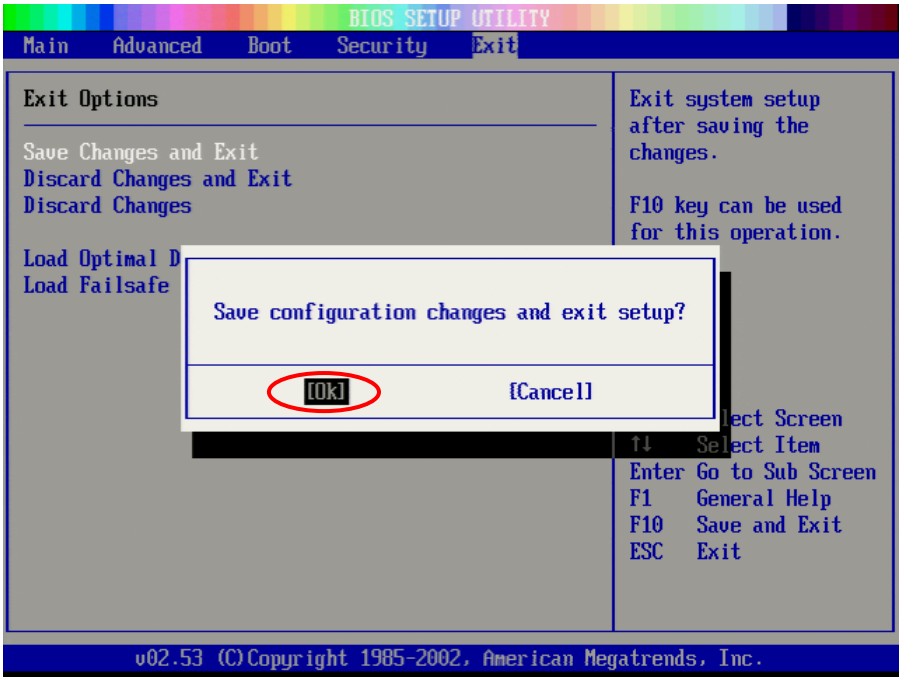


Figure 98 Exit Setup

13. Press **Enter** to confirm OK to Save configuration changes and exit setup.
14. Allow the system to boot.

Restore System Settings/Configure System Settings

- If this is a new installation proceed to set the system settings in the section below based on user preference and local IT requirements.
- If this is a software re-installation then reload the system settings from the previously saved **Capture System Settings Appendix F.pdf** form. This form was saved to a local (non s5i) service computer hard disk as part of the software re-installation procedure.

System Settings

The system is shipped with default settings selected and is ready to image. If you wish to change the default settings, press the **Settings** key on the control panel. The Settings dialog displays.

System Defaults

System defaults are shown in. Figure 99.

1. You can choose to Shut Down or Restart the system.
2. Adjust the date and time if needed. Click the radio button below the Time field to select a Date Format, either M/D/Y, D.M.Y, or Y-M-D. Check **Use 24-Hour Format** to set the date using a 24-hour system.
3. Click **OK** to save your selections.
4. Click **Cancel** if you want to close the system settings dialog without saving your any changes.

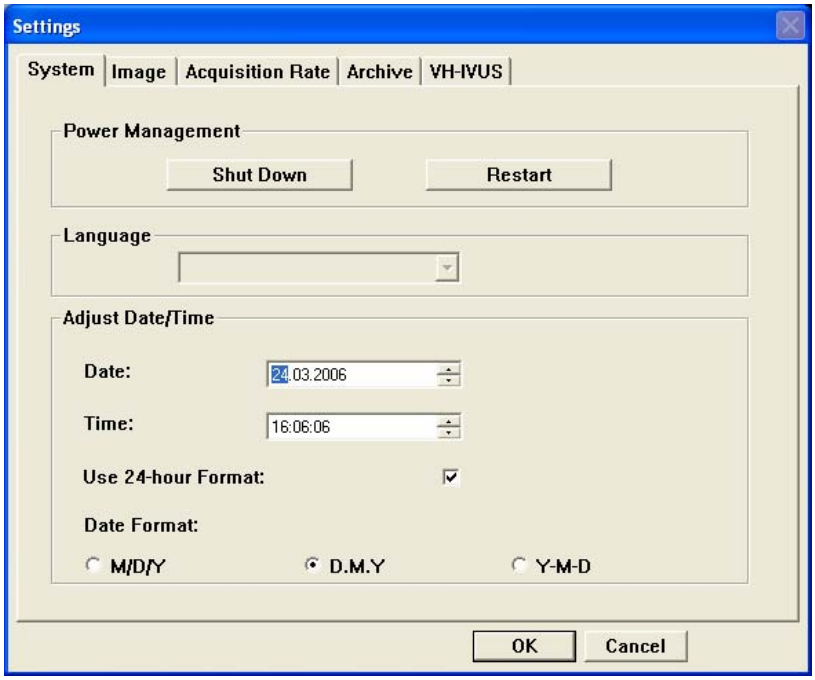


Figure 99 Settings - System Defaults

Image Defaults

System defaults are shown in Figure 100.

- Ring Down Mode
- Pullback prompt–prompt after recording
- Show Graticules

If you wish to change these settings, do so and then click **OK** to save your selections. Click **Cancel** if want to close the dialog without saving your changes.

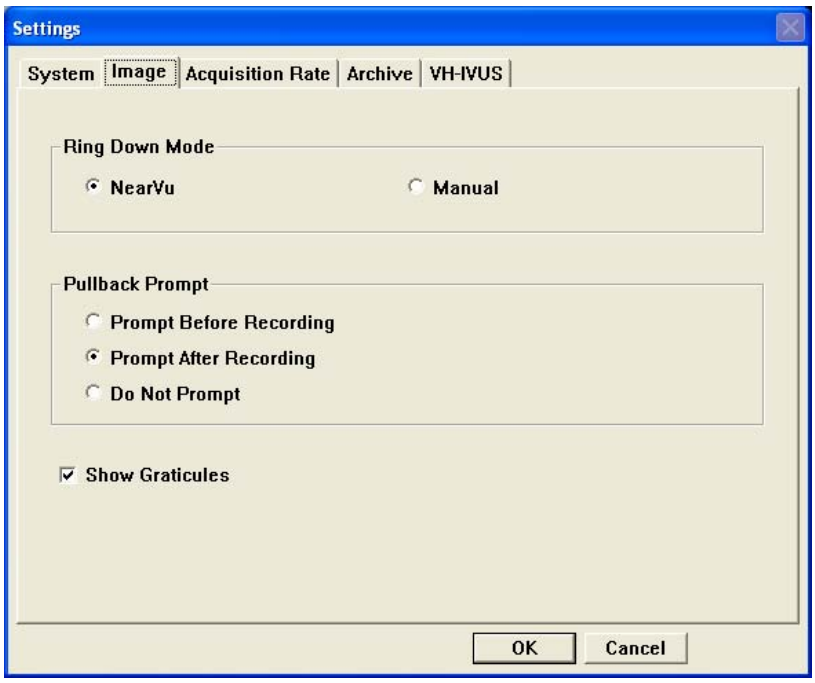


Figure 100 Settings - Image Defaults

Acquisition Rate

System defaults are shown in Figure 101.

Select the **Acquisition Rate/Video Loop Length** parameters you want to use. The choices for the Eagle Eye *Gold* or Avanar catheters are:

- Maximum: Acquire 30 frames per second for a total of 90 seconds per video loop
- Medium: Acquire 15 frames per second for a total of 180 seconds per video loop
- Minimum: Acquire 10 frames per second for a total of 270 seconds per video loop

Rates and video loop lengths are also shown for the PV018 and PV8.2F catheters.

5. Click **OK** to save your selections. Click **Cancel** if you want to close the dialog without saving your selections.

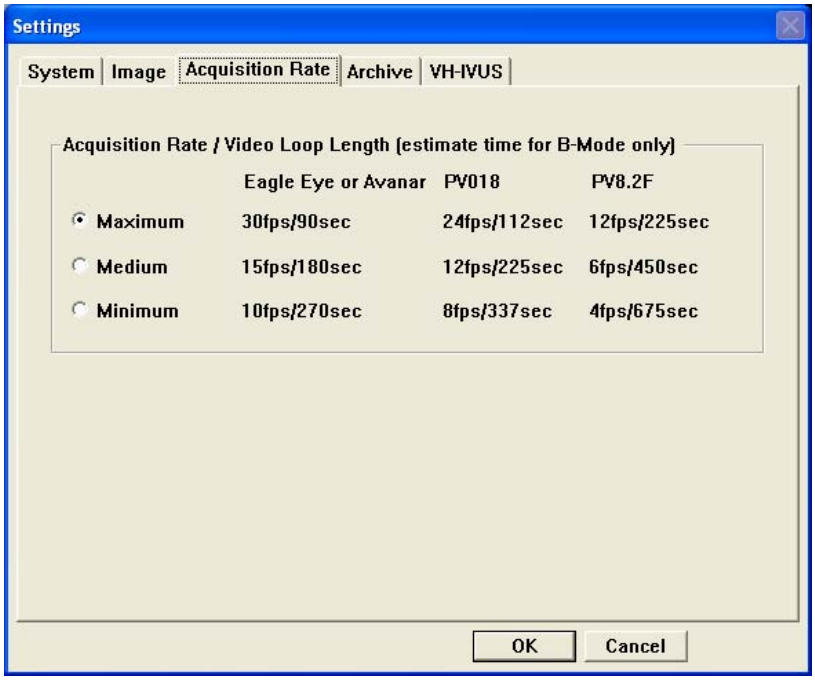


Figure 101 Settings – Acquisition Rate Defaults

Archive Defaults

System defaults are shown in Figure 102.

1. Select the information desired including save frames and recorded loops:
   - Measurements
   - Annotations
   - Graticules

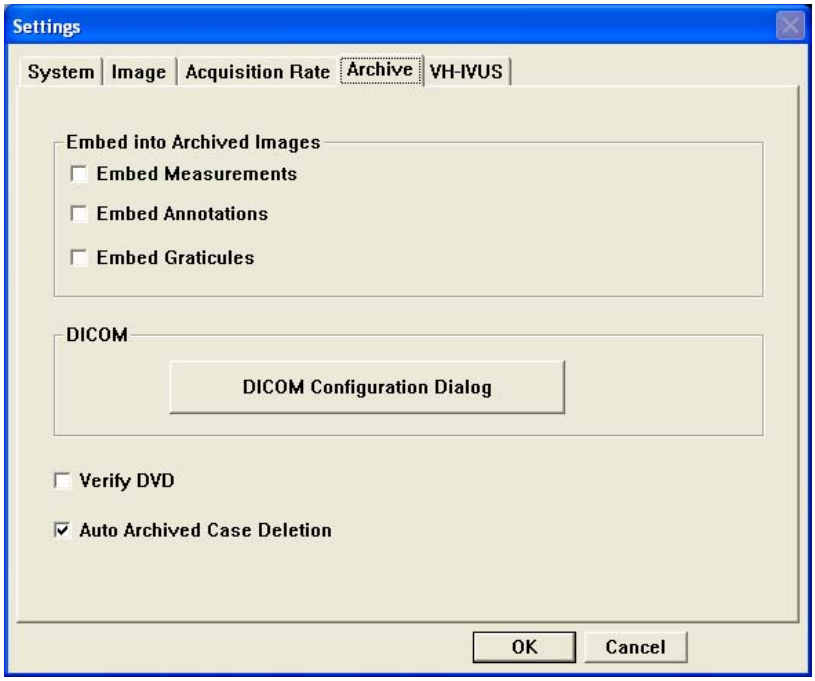


Figure 102 Settings – Archive Defaults

2. Click the **DICOM Configuration Dialog** button to display the DICOM settings dialog box and change the settings.
3. Click **Verify DVD** if you want the system to check for the presence of a DVD in the drive. **Note: Selecting this will take more time to burn a DVD.**
4. Click **Auto Archived Case Deletion** to automatically delete old archived cases.
5. Click **OK** to save your selections. Click **Cancel** if you want to close the dialog without saving your selections.

VH-IVUS

System defaults are shown in Figure 103.

1. Click **VH ON By Default** if you want VH to be on when you start the system.
2. Select the Analysis parameters.
3. Adjust the Default Opacity Levels for each parameter. This allows you to customize the type of tissue color to be displayed, for example, you may be most interested in necrotic (red) tissue.

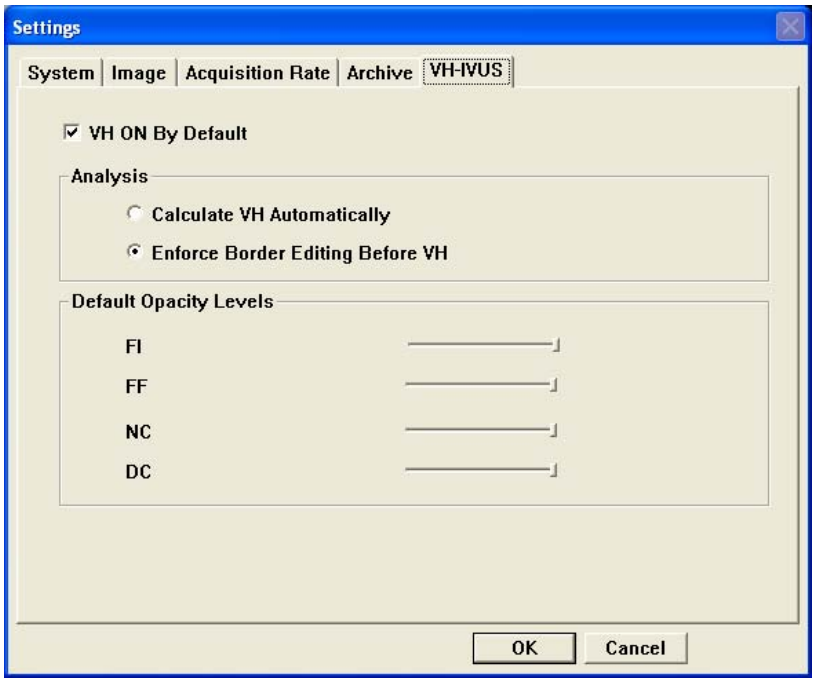


Figure 103 Settings – VH-IVUS Defaults

4. Click **OK** to save your selections. Click **Cancel** if you want to close the dialog without saving your selections

Chapter 7 System Performance Testing

Required Service Tools

Standard FSE Tool Kit	Avanar Imaging Catheter
ESD Kit	DVD -RW/R Diskette(s)
ECG Simulator	RTV Silicon Sealant
Echo Phantom or Test Block	
Eagle Eye Test Catheter	
Visions PV Imaging Catheter	

System Performance Testing

The following procedure details the s5i system performance testing which should be performed after replacement of any system PCA, Hard drive, and software re-ghosting. This procedure will take up to two hours to complete.

Eagle Eye Test Catheter Image Test

1. Locate the Catheter Simulator in the s5i service kit and attach it to the PIM.
2. Compare the image from the Eagle Eye catheter simulator with the printed Catheter simulator reference image, the two images should have the same appearance and overall brightness. If the live image is significantly different from the printed Catheter simulator test image, then replace the Catheter simulator.
3. Select the Adjust Image button on the display.
4. Adjust the Gain to 50.
5. Adjust the Diameter to 8.
6. Select Close.
7. Press the Save Frame button on the console.
8. Select the Adjust Image button on the display.
9. Adjust the Diameter to 10.
10. Enable NearVu by selecting the NearVu check box.
11. Select Close.
12. Verify the image is stable and free of any unusual image artifacts such as noise or excessive transmit ringing. Verify acceptable image resolution, and system gain level.
13. Press the Stop button on the console - the image will freeze.
14. Press the Save Frame button on the console.
15. Press the Home (Live) button on the console.

16. Select the Adjust Image button on the display.
17. Adjust the Diameter to 16.
18. Increase the Gain to its maximum value (68). Select the NearVu check box.
19. Verify the collection area is clear of any near field echoes associated with ring down.
20. Adjust the Gain to 20.
21. Select Close.
22. Press the Save Frame button on the console.
23. Select the Adjust Image button on the display.
24. Adjust the Gain to 50, confirm that the image get's brighter.
25. Adjust the Diameter to 20, confirm that the image gets weaker
26. Select Close.
27. Press the Save Frame button on the console.
28. Select the Adjust Image button on the display.
29. Adjust the Diameter to 10, confirm that the diameter decreases (image enlarges)
30. Select Close.
31. Press the Record button on the console.
32. Slowly move the catheter within the test phantom. After ~ 50 frames, press the Stop button on the console.
33. At the Pullback Rate message box, select '.5mm/second' for the pullback rate and then select OK.
34. Wait for the border detection to complete, confirm that the VH is present on the both the cross seciotnal display and the in line digital display (longitudinal display).
35. Select the Live button on the display, and confirm a "live" image.
36. Select Home on the Console keyboard.

Annotation and Measurements

1. Press the Measure button on the console.
2. Verify the saved frame measurements.
3. Select Case Explorer.
4. Select the saved frame, 'F1Live.
5. Select the VH button on the console.
6. Select the Measure Diameter radio button on the display (if not already selected).
7. Perform an (x)(x)-(y) (y), line trace from the left graticule to the right graticule, press select and from top graticule to bottom graticule Verify the diameter (actual 6.0mm diameter in water with tolerance +/- 0.1mm).
8. Move the cursor over the displayed image and use the notebook keyboard to type through the Alphabets (Upper and lower case) and numbers (0-9).
9. Verify the Video loop measurements are present.
10. Move the cursor over the area on the display labeled Case Explorer.
11. Select the Video loop, 'VL1: SOI1', on the Active Case tree.
12. Move the cursor within the Sagittal view section.

13. Left click within the Sagittal view section, and move the cursor up or down until the measurement is 1.0, then left click again (This is now the section of interest)
14. On the right side of the Sagittal view, left click on the Green measure marker and drag it to the beginning of the measurement. Left click again to disengage the marker.
15. Left click on the Red measure marker and drag it to the end of the measurement. Left click again to disengage the marker.
16. Select the Play button on the display. The section of interest Video Loop should take 2 seconds from beginning to end.
17. Press the Stop button on the console.
18. Press the VH button on the console.
19. The video loop should now display with VH.
20. When moving the cursor over the Pie chart on the display, it should give you the statistics associated with that frame.
21. When you click on the Pie chart, more information is displayed at the bottom of the image.
22. Select the Vessel check box and Start Edit button in the tool bar.
23. Select a point along the outside VH border on the image (between the circles).
24. Move the border further out from where it originally was and then left click again.
25. Select one of the circles along the outer border.
26. Move the circle and click again.
27. With each of these edits, the Vessel border should have moved.
28. Select the Lumen check box.
29. Select one of the circles on the Lumen borders and move it inward. Then left click again.
30. Select a point between the circles, and move the border. Click again.
31. With each of these edits, the Lumen border should have moved.
32. Select the Reanalyze button.
33. The system will re-calculate with the new borders.
34. Move the cursor over the area on the display labeled Case Explorer.
35. Select the Video loop, ‘VL2: SOI1’.
36. Select the green play button on the display.
37. During the playback, press the Bookmark button on the console three times.
38. Press the Stop button on the display.
39. Move the cursor within the Sagittal view section.
40. Create another section of interest, 1mm in length.
41. Mark the beginning and end of the section of interest.
42. Select the Play button on the console. The section of interest Video Loop should take 2 seconds from beginning to end.
43. Press the Stop button on the console.
44. Move the cursor over the area on the display labeled Case Explorer.
45. Select the Bookmark, ‘BMK1’, on the Video Loops and Still Frames tree.
46. The image displayed should now be where the Bookmark button was first pushed.

47. Use the up/down arrows labeled NAVIGATE BOOKMARKS Select the other two bookmarks using Case Explorer, and verify the image changes to the selected bookmarks.
48. Use Case Explorer to select, 'F2Live'.
49. Select the Measure Area radio button on the display.
50. Move the cursor to the top of the Inner Diameter (I.D.) for the test block's image. Left click and draw along the I.D. of the circle.
51. Before completing the circle, stop and press the "-" button (Right click) several times to demonstrate the erase feature.
52. Continue to trace the I.D. of the circle and then left click again.
53. The 2 length measurements should be 6 mm +/- 10% (0.6 mm) each, and the area measurement (B1) should be 29 mm² +/- 22%.(6.4 mm^2)

Page Printer Test

1. Select Video loop, 'VL1: SOI1'.in the Case Explorer area.
2. If VH is not active, then select the VH button on the console.
3. Find a frame within the video loop that shows an assortment of the VH colors.
4. Left click on the Pie Chart.
5. Press the PRINT button on the console.
6. After the printer has finished printing the image, press the Display button on the console. The Image should become most of the display.
7. Press the PRINT button again on the console.
8. After the printer has finished printing the image, press the Display button again. The Image should go back to normal.
9. Verify the print for: Clarity and accurate reproduction, image within print border and acceptable contrast, brightness and color levels.

DVD-R Drive Check

1. Open the DVD-R drive's tray, and insert a blank DVD-R diskette, and close the drive tray.
2. Select the DVD-R Media radio button. Highlight the current case.
3. Select **Start Archive**.
4. After the case is stored to DVD, the DVD-R tray will open to eject the disk.
5. Close the tray with the disk still on the tray.
6. Highlight the current case again.
7. Select **Delete Case** on the display. Select **Yes**, to continue deletion.
8. Select the RETRIEVE tab on the display.
9. Select the DVD Media radio button, and highlight the file.
10. Select **Start Retrieve**.
11. After the case has been loaded back onto the system, verify that all of the saved frames, bookmarks and video loops were loaded and not corrupted.
12. Eject and remove the DVD-R disk from the DVD-R drive. Close the drive's tray.
13. Select the Archive tab.

14. Delete all cases displayed by highlighting the case, selecting the Delete Case button and then selecting Yes, to continue the deletion.
15. Repeat this step until all cases are deleted and the system displays the Patient Information Screen.
16. Delete any Patient information entered for testing.

Viewing the SMPTE Image

1. The video subsystem can be tested using the shareware program Nokis Monitor Test V1.0 which is located on the service disk in the following foler /Documents/mon_test/
2. Install the Service Disk into the DVD drive bay.
3. Log into the advanced user's service mode (see Appendix A).
4. Launch Windows explorer and navigate to the DVD drive folder E:/Documents/mon_test
5. Double click on the monitor test program.

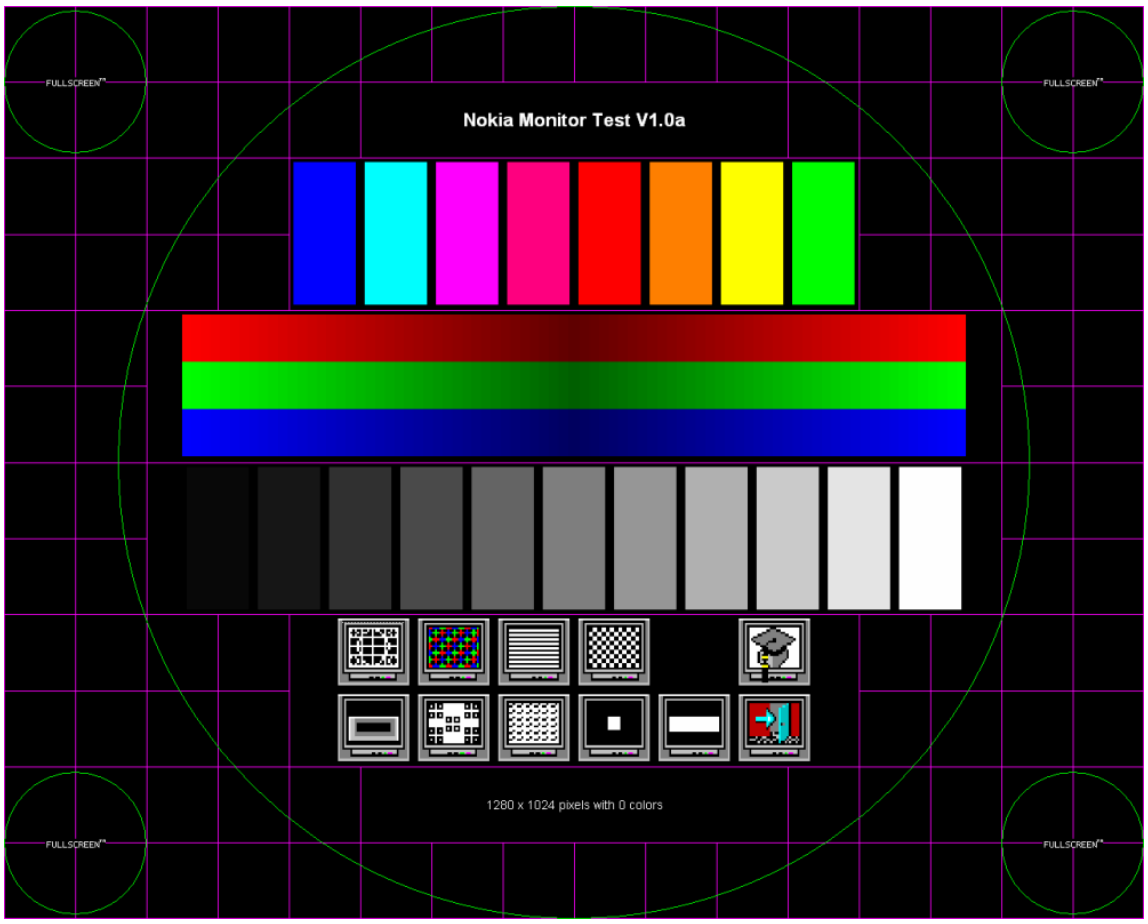


Figure 104 Nokia Monitor Test Program

6. Utilize the available test patterns as required.

Preventative Maintenance Checklist

SYSTEM SERIAL # :
PIM SERIAL NUMBER: 0500-0
MONITOR SERIAL NUMBER:
DIGITAL PCA SERIAL NUMBER:
DIGITAL PCA REVISION:

DVD TYPE:
PRINTER TYPE:
MONITOR TYPE:
SOFTWARE VERSION: . .
DICOM INFO:

ITEM		
INSPECT WORKSTATION FOR PHYSICAL DAMAGE	O	DAMAGED:_____
INSPECT PIM FOR PHYSICAL DAMAGE	O	DAMAGED:_____
INSPECT CONTROL PANEL FOR PHYSICAL DAMAGE	O	DAMAGED:_____
INSPECT ISOLATION TRANSFORMER FOR PHYSICAL DAMAGE	O	DAMAGED:_____
INSPECT ALL CONNECTIONS AND CABLE FOR PHYSICAL	O	DAMAGED:_____
INSPECT ALL PERIFERAL DEVICES FOR PHYSICAL DAMAGE	O	DAMAGED:_____
CONFIRM THE SYSTEM BOOTS UP TO THE IMAGE SCREEN	P	F
TEST CATHETER IMAGE QUALITY	P	F
CONFIRM COMMUNICATION TO THE WORKSTATION PERIERALS	P	F
CONTROL PANEL FUNCTIONS	P	F
ECG SIGNAL	P	F
MONITOR QUALITY	P	F
SETUP MENU FUCTIONS	P	F
ANOTATIONS AND MEASUREMENTS	P	F
RING DOWN	P	F
IMAGE MENU FUCTIONS	P	F
PRINT FUNCTION/PRINT QUALITY	P	F
PATIENT	P	F
MENU	P	F
BOOKMARK	P	F
SELECT	P	F
FILE MENU FUNCTIONS	P	F
MEASURE	P	F
CHROMA	P	F
HOME (LIVE)	P	F
KEYBOARD FUNCTIONS (ALL KEYS)	P	F
RECORD	P	F
STOP	P	F
PLAY	P	N
ARCHIVE & RETRIEVE DATA HARD DRIVE/DVD/DICOM	P	N
DICOM CONFIGURED	Y	N
TEST PATTERNS	P	F
REMOVE DVD DISKETTE	Y	N
REMOVE TEST CASES FROM HARD DRIVE	Y	N
REMOVE RECORDING MEDIA	Y	N
CONFIRM SHUT DOWN PROCESS	Y	N
REMOVE TEST CASES FROM HARD DRIVE	Y	N
LIST ANY DEFECTIVE OR DAMAGED COMPONENTS BELOW AND DISPOSITION:	Y	N

FIELD SERVICE _____ _____

Chapter 8 Troubleshooting

Troubleshooting Chart

PROBLEM	DIAGNOSIS	ACTION
System does not power up.	▪ There is an AC power interruption to the system	▪ Check that the Power cords are properly plugged in to the correct power sources. o NOTE: The CPU Power supply fan never shuts off if AC power is supplied. ▪ Check that the Isolation Transformer power toggle switch is turned on and that the isolation transformer has been set for the correct voltage. o If the Isolation Transformer was not set to the correct voltage, the fuses are likely blown. ▪ The Power button for the CPU is the large black button adjacent to the Volcano Logo on the front panel. o When the CPU is operating the power indicator should be lit, the hard drive access indicator may be blinking and all of the system fans should be running. ▪ Listen for an Error Beep Code at boot time. The Error Beep codes can be found in Motherboard Audible and Visual Alarms on page 194. Check CPU system DC power
No VGA Video is displayed.	▪ There is an AC power interruption to the system ▪ There is a video signal interruption ▪ The monitor is damaged	▪ If there is no display on the monitor, check that the monitor and video signal path hardware (switches and buffers) are properly connected to the correct power source and all devices are powered on. ▪ Listen for Error Beep Code from motherboard. Error beep codes can be found in Motherboard Audible and Visual Alarms on page 194. ▪ Check the video signal path cabling. Insure that the correct ports on the video switch are employed and the switch is set to the correct channel. ▪ Debug the video chain using another video source and temporarily jumping around the accessory hardware where possible.

PROBLEM	DIAGNOSIS	ACTION
Only one of the monitors is displaying the User Interface.	▪ There is an AC power interruption to the system ▪ There is a video signal interruption ▪ The monitor is damaged	▪ Verify monitors are connected. ▪ One of the monitors was disconnected or not on during boot. Turn both monitors on, insure connectivity, and reboot. If problem persists, enter the Windows desktop thru the field service mode and run the ATI control manager. Verify that both monitors are enabled
Operating System fails to boot.	▪ Possible DC power interruption ▪ Mechanical error, parts not seated/mounted correctly ▪ Hard drive data corruption	▪ Check CPU system DC power. ▪ Check system BIOS settings to insure SATA is set to first channel. ▪ Check that the hard drives are properly seated into their connectors. ▪ Observe possible error messaging and debug for defective accessory hardware or interconnection failures. ▪ Swap hardware with re-loaded drives or use install CD's to reinstall system OS. ▪ **! CAUTION** – Reloading the OS and software will delete all files from the system hard drives. Patient Data on the second hard drive will be wiped in this process. Be sure that this information has been properly backed up.
No IVUS display.	▪ Defective hardware ▪ Interconnection failures	▪ Insure PIM is connected. ▪ Insure catheter or catheter simulator is connected and not defective. ▪ Insure that the two Meridian boards (Analog and Digital) are properly seated together and in the PCI slot. ▪ Insure that the analog filter cards are not loose on the Meridian analog board. ▪ Meridian Imaging boards may be defective, replace imaging boards.
Video display appears to be lacking a fundamental color or is only Red, Green, or Blue.	▪ The DVI connector is not fully seated and screwed in. ▪ Video cable may have broken wire.	▪ Check DVI connector, seat and screw in if necessary. ▪ Replace video cable.
Graphical user interface image is not aligned on screen. (Slightly off screen to one edge of display.)	▪ The LCD monitor did not switch modes correctly.	▪ Reboot the monitor or use the monitor menu structure to initiate a re-scan of the video synchronization.
IVUS image is vertically or	▪ The monitor is not set to true aspect ratio display mode.	▪ The native display mode for software version 2.2 and later is 1280x1024. Reset

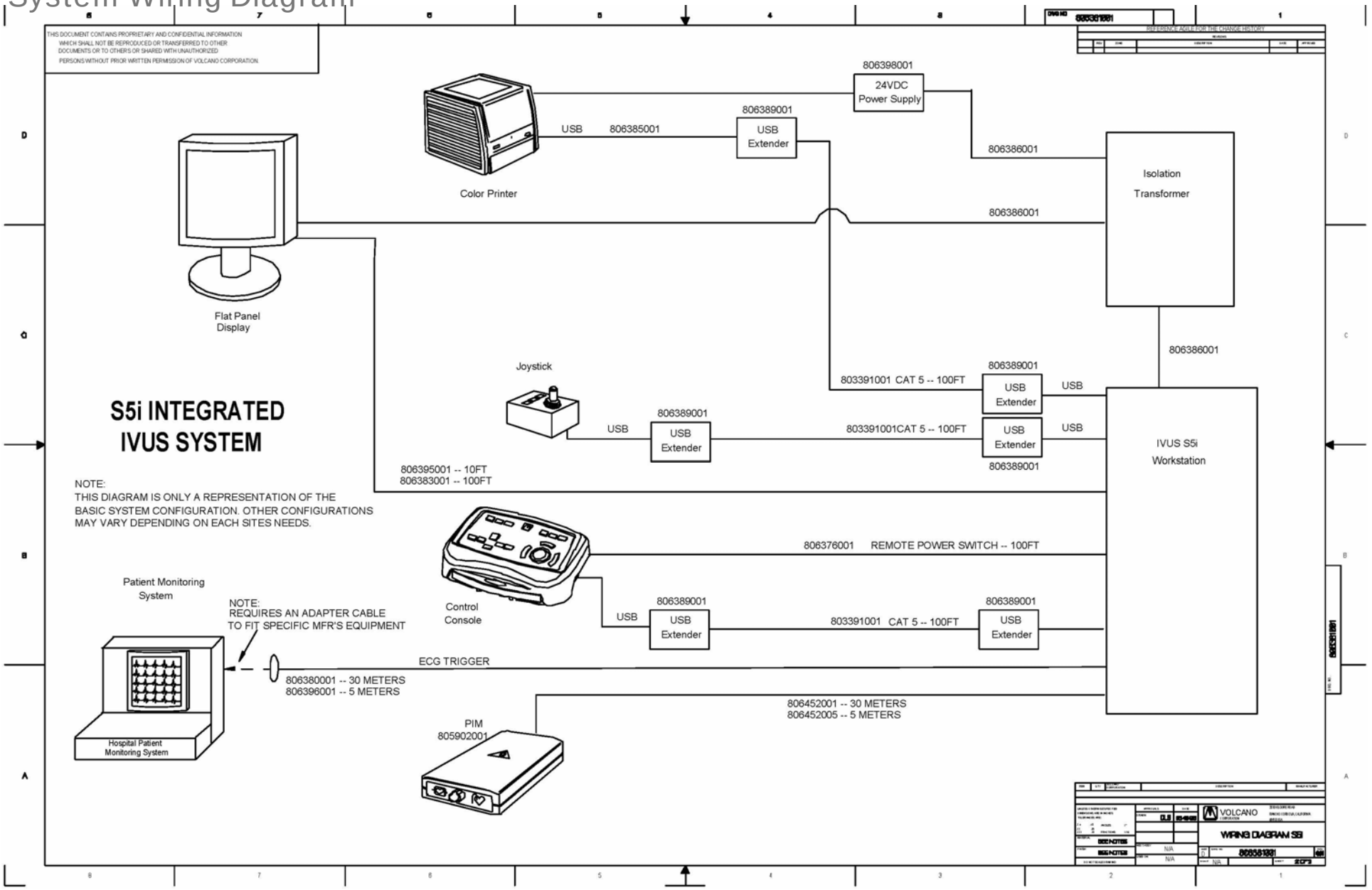
PROBLEM	DIAGNOSIS	ACTION
horizontally ellipsoid shaped.		monitor resolution.
IVUS display is noisy.	▪ Usually caused by pick-up from extraneous equipment, radiating EMI at the transducer frequencies	▪ Ascertain offending equipment and shut down if possible. ▪ Install Ferrite Toroid on radiating cabling. ▪ Notify Field Service, specific fixes for some equipment have been developed.
System boots to Volcano logo screen. Mouse cursor is active, but no user interface appears.	▪ The user interface may be in the background ▪ The system hard drive may be corrupt or defective.	▪ Press the Escape key to force the USER INTERFACE to the foreground. ▪ Attempt a reloading of the OS. ▪ **! CAUTION** – Reloading the OS and software will delete all files from the system hard drives. Patient Data on the second hard drive will be wiped in this process. Be sure that this information has been properly backed up. ▪ If reload is unsuccessful, replace the hard drive 0.
No Heart-beating icon with ECG input, No VH data.	▪ Improper ECG signal being used ▪ Cabling not fully connected. ▪ VH imaging card may be defective	▪ Utilize the ECG simulator (included in the service kit) if the Heart beats with the simulator then insure that the ECG input is a proper high-line signal and that the interconnection cabling is properly connected into the correct input connector. ▪ Insure that the jumper cable is installed between the Meridian digital board and the VH board. ▪ Replace VH board.
PIM not Found Error Message.	▪ Cabling not fully connected. ▪ Bent connector pins ▪ PIM damaged	▪ Check that the PIM is properly connected to the system cabling. ▪ Check that the connectors do not have bent pins. Replace damaged pins, or board if necessary. ▪ Check that the PIM is not physically damaged. ▪ Check for error messages during the OS boot time.
Catheter Type not recognized.	▪ Install error ▪ Contamination or corrosion on the pins or the sockets in the PIM catheter connections ▪ Mechanical damage to PIM ▪ Damaged catheter	▪ Disconnect catheter from PIM, wait three seconds and reinstall catheter. ▪ Repair or replace any corroded or contaminated components on the pins or the sockets in the PIM catheter connections. ▪ Check PIM for physical damage. ▪ Replace catheter.

PROBLEM	DIAGNOSIS	ACTION
Unable to archive to DVD.	▪ Improper media being used ▪ Cases not selected ▪ Software error in finding DVD drive. ▪ Defective DVD drive.	▪ Insure only DVD-R media is attempting to be used. ▪ Insure selected cases are highlighted. ▪ Check the CMOS and insure that the computer can find the DVD drive. ▪ Check the drive operations thru the field service mode access to the desktop. o Insure File Explorer can see the drive and access files on a known good DVD. o Use Nero and insure that the drive will write to media. ▪ If operations fail, the drive is probably defective. Replace DVD drive
Unable to archive to DICOM.	▪ Cabling not fully connected. ▪ Network set-up error ▪ Incorrect IP address	▪ Insure network cabling is properly connected ▪ Check network setup dialog box. To correctly answer these questions may require assistance from the facility IT staff. o Insure network system is up and legal port is accessed. ▪ Insure IP addresses are correct
Control Panel keys do not work.	▪ Cabling or extender not fully connected ▪ Damage to or adhesion on keys of control panel. ▪ Damaged USB extender ▪ Damaged or defective Control Panel	▪ Insure that the USB cables and the extender properly are connected. ▪ Check the Control panel for physical damage ▪ Insure that no buttons are stuck depressed. ▪ If the trackball works, but the keyboard does not then the keyboard is defective, replace the Control Panel. ▪ Check the USB extender for operation, by substituting another USB extender or moving the suspect extender to another interface. If it fails replace the USB extender. ▪ Replace the Control Panel.

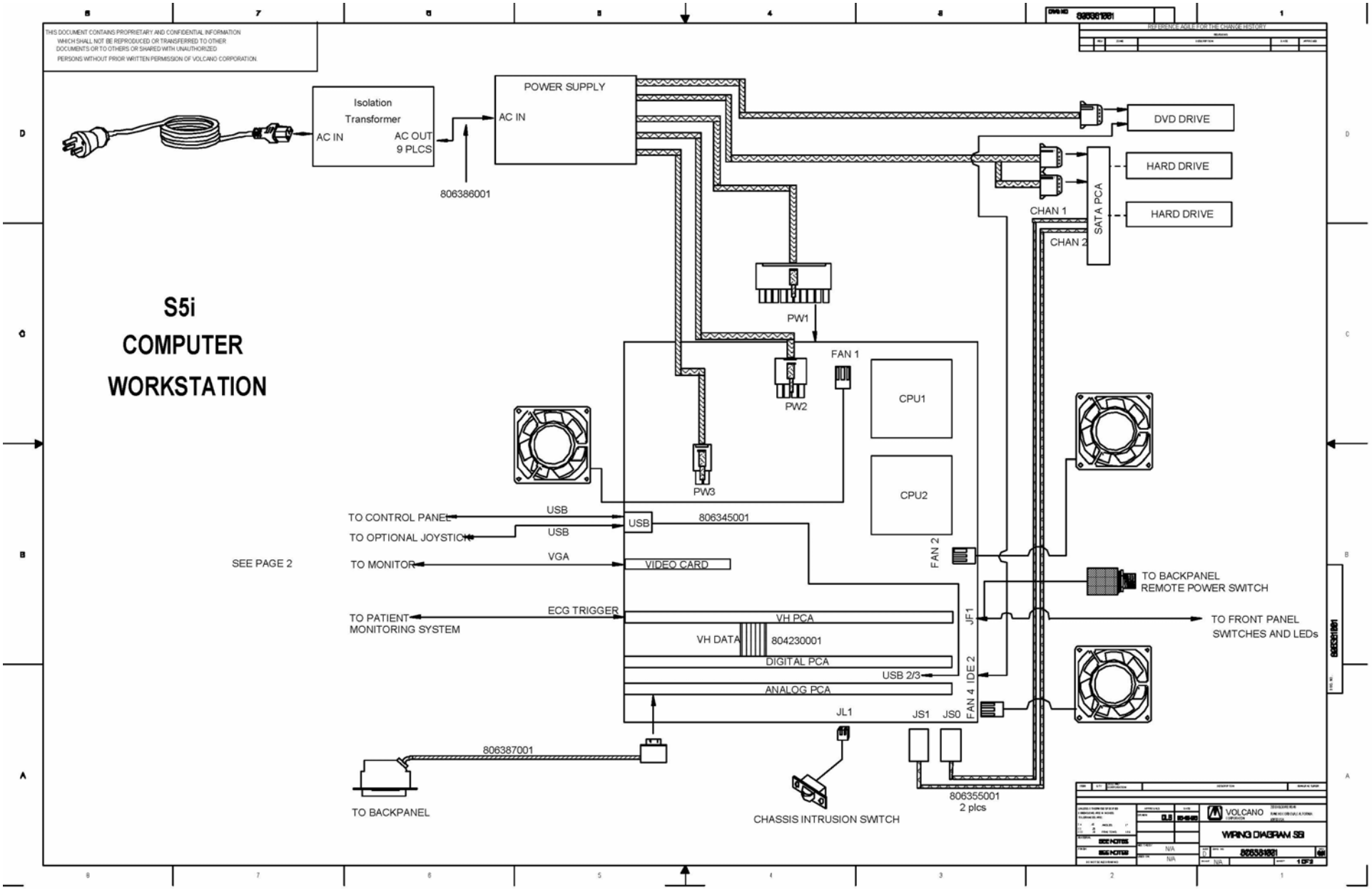
PROBLEM	DIAGNOSIS	ACTION
The Trackball does not work properly.	▪ Cabling or extender not fully connected ▪ Damaged USB extender ▪ Damaged or defective Control Panel. ▪ Damaged or defective Trackball.	▪ Insure that the USB cables and the extender are properly connected. ▪ Check the Control panel for physical damage, replace if necessary. ▪ If the keyboard works, but the trackball does not, then the trackball is defective, replace the Control Panel. ▪ Check the USB extender for operation, by substituting another USB extender or moving the suspect extender to another interface. If it fails, replace the USB extender. ▪ The Trackball may be defective, replace the Control Panel.
Joystick controller only has one axis of movement (X or Y).	▪ Damaged or defective Joystick ▪ Damaged USB extender	▪ Check USB connectivity by swapping with a Control Panel. ▪ Joystick may be defective
Printer does not work.	▪ Cabling or extender not fully connected	▪ Check that the printer is turned on. ▪ Insure that the Printer has paper and a functional print ribbon. ▪ Check that the USB cabling and the Printer power cabling is properly connected. ▪ Using the Windows desktop thru the Field Service mode, check that the printer is set to default printer. o Changing the USB configuration from a USB extender to the chassis USB connector or vice-versa will change the printer such that the previous default will be lost. ▪ Using the Windows desktop, insure that the Print Manager is running on the taskbar. ▪ Using the printer function on the desktop, initiate a test printout. ▪ The printer may be defective, replace the printer

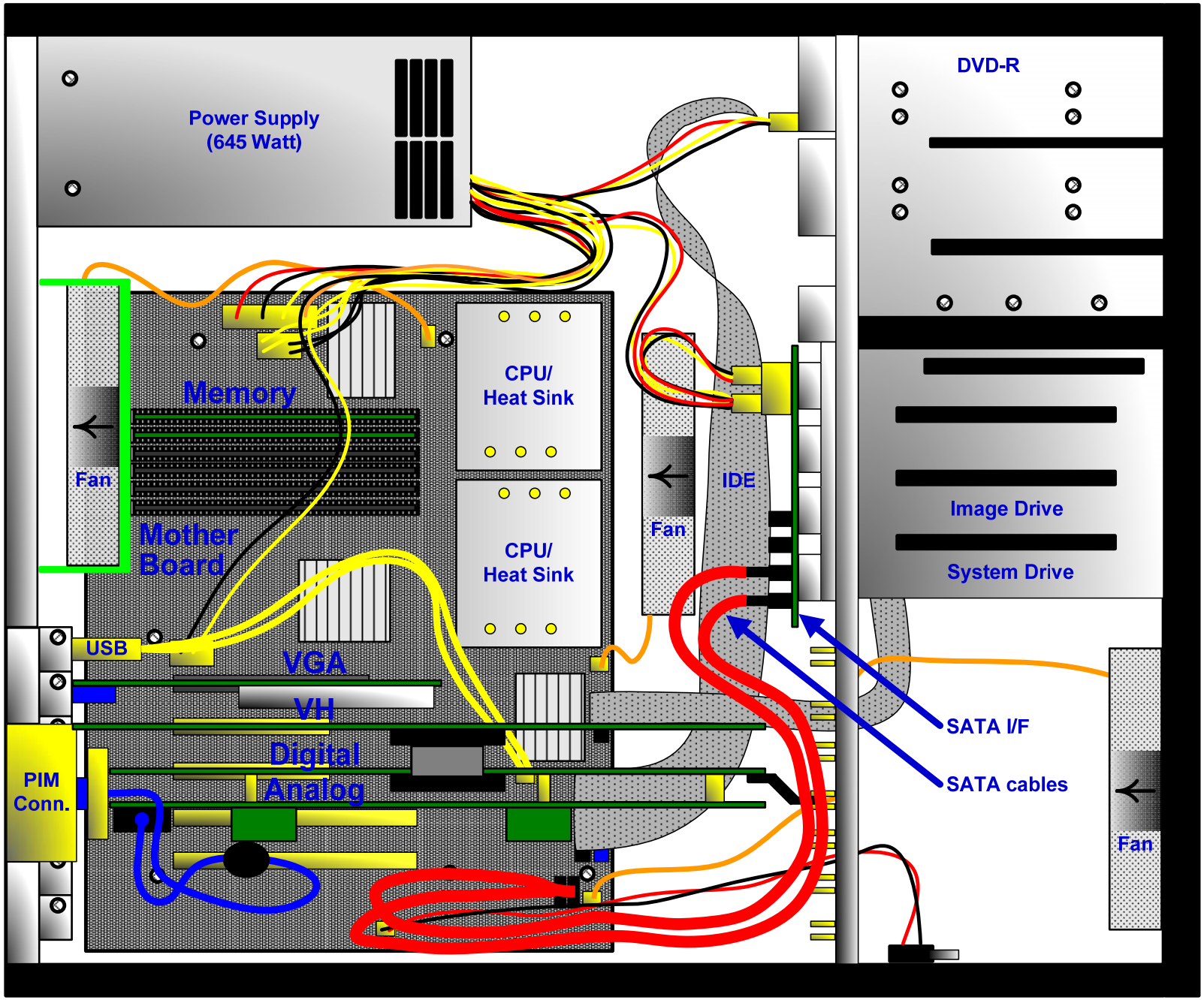
Chapter 9 System Diagrams and Part Lists

System Wiring Diagram



CPU Wiring Diagram




Power Supply
(645 Watt)
DVD-R
Memory
CPU/
Heat Sink
Fan
IDE
Mother
Board
CPU/
Heat Sink
Fan
Image Drive
System Drive
USB
VGA
VH
Digital
Analog
PIM
Conn.
SATA I/F
SATA cables
Fan

(s5i) Part List

Agile PN	Qty	Description
		s5iGE IMAGING SYSTEM 806300-003/003
		s5iGE PC & SYSTEM Components Kit 806301-013/001
806301001	1	PC MODULE ASSY
806709001	1	s5i Control Room Monitor Option Kit
805902001	1	PATIENT I/F MODULE s5i
806358001	1	PIM mounting bracket, s5i
806329001	1	isolation transformer
806395001	1	Cord set VGA 10ft
806396001	1	CA ECG/BP Twin-axial 5m
806394001	1	Cord set Cat5E 14ft
804635001	1	DVD Disk
806859001	0	label, S5I STANDARD SYSTEM COMPONENTS
806859004	0	LABEL, S5I ISOLATION TRANSFORMER
806311001	1	Label, System Rating
804255002	1	s5i SOFTWARE APP GHOST INSTALLATION DVD
804255003	1	s5i SOFTWARE OS GHOST INSTALLATION DVD
806751001	0	VOLCANO S5i INSTALLATION QUALIFICATION
804488001	1	DEVICE IQ/OQ RETURN ENVELOPE
804209002	1	User Manual CD
806365002	1	Service Manual CD
805950001	1	ECG simulator
806058001	1	EE catheter simulator
806302001	1	s5I Control Console SUB ASSY
806384001	1	Pre-Installation Cable Kit 30m
		s5iGE IMAGING SYSTEM Kits
		Optional Control Console/Keyboard, S5IGE 806302-009
806302001	1	s5I Control Console SUB ASSY
806713002	1	Control Console Rail Bracket Kit, S5IGE
		Control Console Rail Bracket Kit, S5IGE 806713-002
806717001	2	CLAMP RAIL, JOYSTICK, S5I
806326001	1	RAIL BRACKET, S5I
S2800257	6	WASHER INT STAR #10MCMASTER 91113A011
S2800126	6	WASHER INT STAR #8
S2800254	6	SCREW PANHD PHIL 10-32 X3/8 MCMSTR 90272A827
806461001	6	SCREW, PNHD PHIL, #8-32 X 1/2L, ZNC
806715001	2	1/4-20 X 3.0" ALUMINUM CLAMPING KNOB
806389001	1	USB Extender
806859007	1	label, rail bracket kit, s5iGE
806397001	1	CA EQUIPOTENTIAL GROUND HAMPDEN PLUG (GE Only)
		Joystick Option Kit, S5IGE (806695-002)
806371001	1	Joystick Assy
804526001	1	BOX, RPD PACKING
806731003	1	LABEL, PACKAGING, JOYSTICK, S5IGE

806397001	1	CA EQUIPOTENTIAL GROUND HAMPDEN PLUG (GE Only)
806389001	1	USB Extender
		s5i Software Installation Kit (804255004)
804255002	1	s5i SOFTWARE APP GHOST INSTALLATION DVD
804255003	1	s5i SOFTWARE OS GHOST INSTALLATION DVD
		CPU fan Kit (806809001)
806352001	3	PC FAN NEON LED 120X120X25MM 12VDC
		CPU Cable Kit (806810001)
806387001	1	CA ANALOG TO BACKPANEL
806378001	1	CA Remote Power Switch PC
806355001	1	CA SATA CABLE
804230001	1	CA ASSM VH DATA INTERCONNECT MERIDAN
		VOLCANO S5I IMAGING BOARDSET (806088003)
802347001	1	ANALOG BOARD PCA
802348001	1	DIGITAL BOARD PCA
804311001	1	DIGITAL VH BOARD PCA
802929001	1	PCA, MERIDIAN BANDPASS FILTER - 10MHZ STANDARD
802930001	1	PCA, MERIDIAN BANDPASS FILTER - 20MHZ STANDARD
802931001	2	PCA, MERIDIAN LOWPASS FILTER-10 + 20MHZ STANDARD
804230001	1	CA ASSM VH DATA INTERCONNECT MERIDAN

Chapter 10 Removal and Replacement Procedures

Safety Precautions

Always wear an ESD wrist strap when working with static-sensitive devices and PCAs. Unplug the system prior to disassembly

Required Service Tools

Standard FSE Tool Kit	Avanar Imaging Catheter
ESD Kit	DVD -RW/R Diskette(s)
ECG Simulator	RTV Silicon Sealant
Echo Phantom or Test Block	
Eagle Eye Test Catheter	
Visions PV Imaging Catheter	

Preparation for Parts Removal / Installation

Archive Saved Data

Archive all saved data to DVD-R diskettes or DICOM network prior to servicing or performing system upgrades.

Complete the **Capture System Settings Form** found in Appendix F and save to a local (non s5i) hard drive for post repair system settings restoration.

Turn the system off.

s5i PC Module Access Cover Removal

Unplug the AC power cord to the isolation transformer

.Disconnect all cables to/from the s5i workstation:

- Power Cord
- PIM Cable (37 pin D Connector)
- Safety Ground Wire
- All USB connections
- All Video Connections
- ECG Connection
- Ethernet (RJ45 LAN) Connection
- PS2 Keyboard and touchpad (if present)

Place the s5i PC module on an ESD mat.

Remove PC module Access Cover (see Figure 105 below).

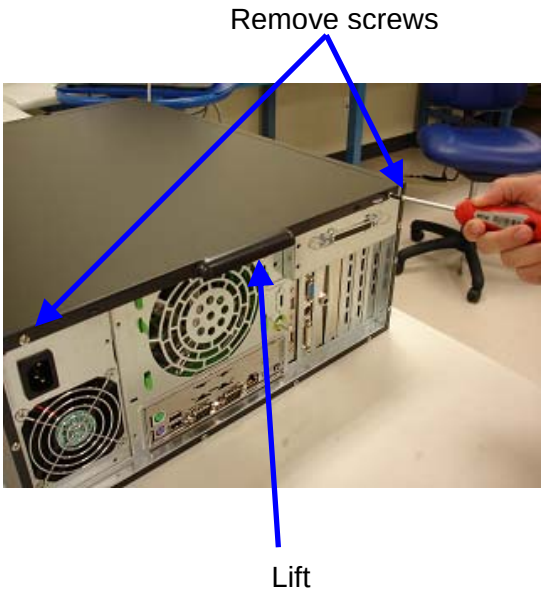


Figure 105 Removing CPU Cover

Hard Drive Removal / Installation

Removal

- Perform steps outlined in section Preparation for Parts Removal / Installation on page 126.
- Use key to unlock front panel and open.
- Push button to release drive latch.
- Pull out hard drive.
- Unscrew the 6 screws (3 on each side) and remove drive from frame.

Figure 106 Removing Hard Drive

Installation

- Replace the 6 screws to secure drive in frame.
- Push new hard drive into drive slot.
- Push securing latch back in.
- Replace front panel and use key to lock in place.

Video Board Removal / Installation

Removal

- Perform steps outlined in section Preparation for Parts Removal / Installation on page 126.
- Remove the 1 screw that secures board to PC chassis.
- Gently pull Video Board up and out.

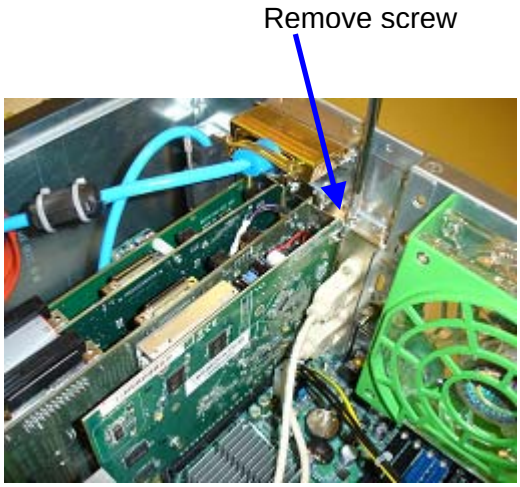


Figure 107 Removing Video Board

Installation

- Align Video Board with Receiver and push back into place.
- Replace the 1 screw to secure to PC chassis.

Analog / Digital Board Removal / Installation

Removal

- Perform steps outlined in section Preparation for Parts Removal / Installation on page 126.
- Unscrew the 2 screws holding PIM connector onto back panel and remove PIM connector from the back panel.
- Remove the 1 screw holding board set.
- Remove the cable between the VH card and the Digital card (see Figure 108 below).
- Gentle depress the release tab and pull up on Analog / Digital Board.

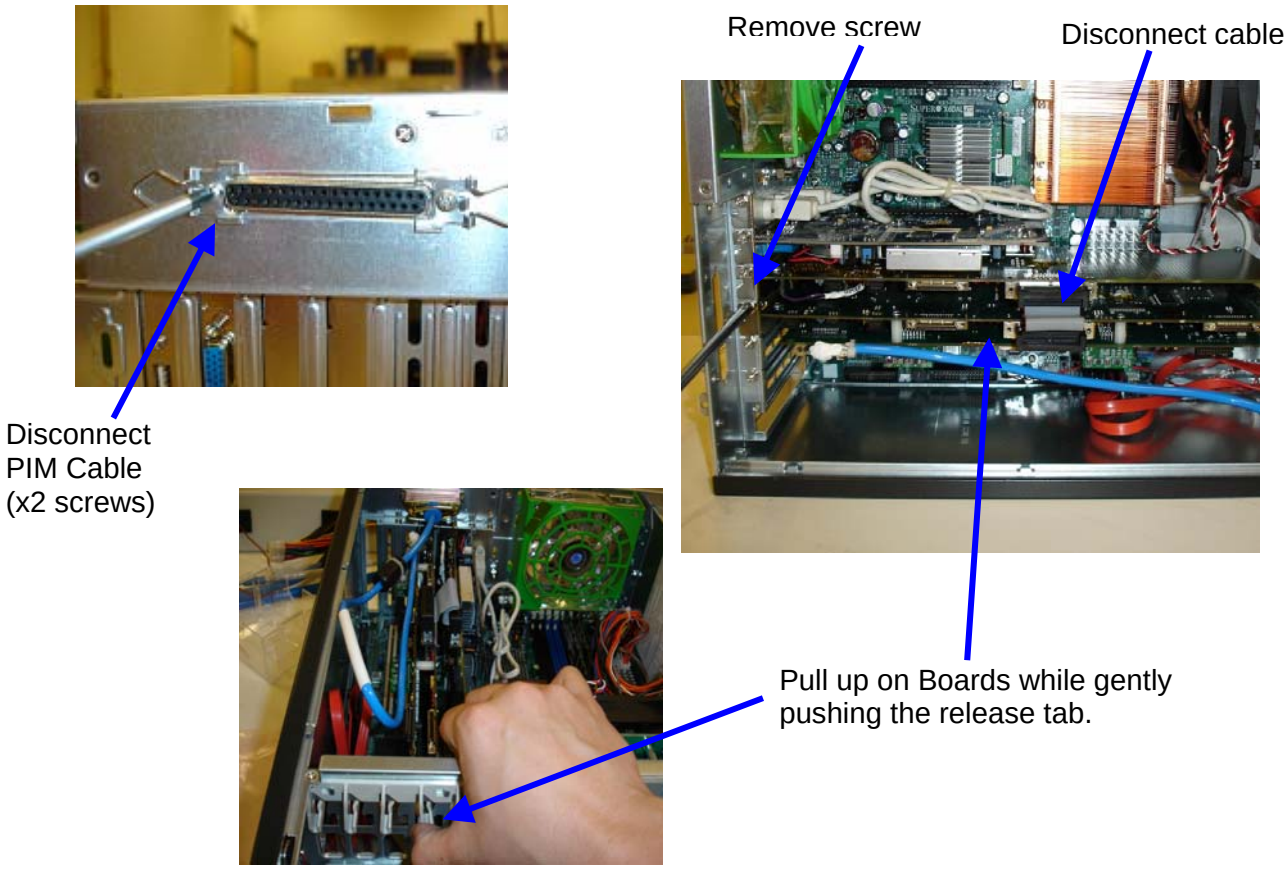


Figure 108 Removing Analog Digital Board

Installation

- Align board with receivers.
- Gently push Analog / Digital Board into place.
- Replace plug connecting VH Board and Analog / Digital Board
- Replace the 1 screw holding board in.
- Replace the PIM connector and the 2 screws that hold connector to back panel.

VH Board Removal / Installation

Removal

- Perform steps outlined in section Preparation for Parts Removal / Installation on page 126.
- Unscrew the 2 screws holding PIM connector onto back panel and remove connector.
- Disconnect PIM cable from VH Board.
- Disconnect cable between VH Board and the Analog / Digital board.
- Remove the screw securing the VH card to the workstation.
- Gently push the tab over to release board while slowly and gently pulling up on Analog / Digital board.

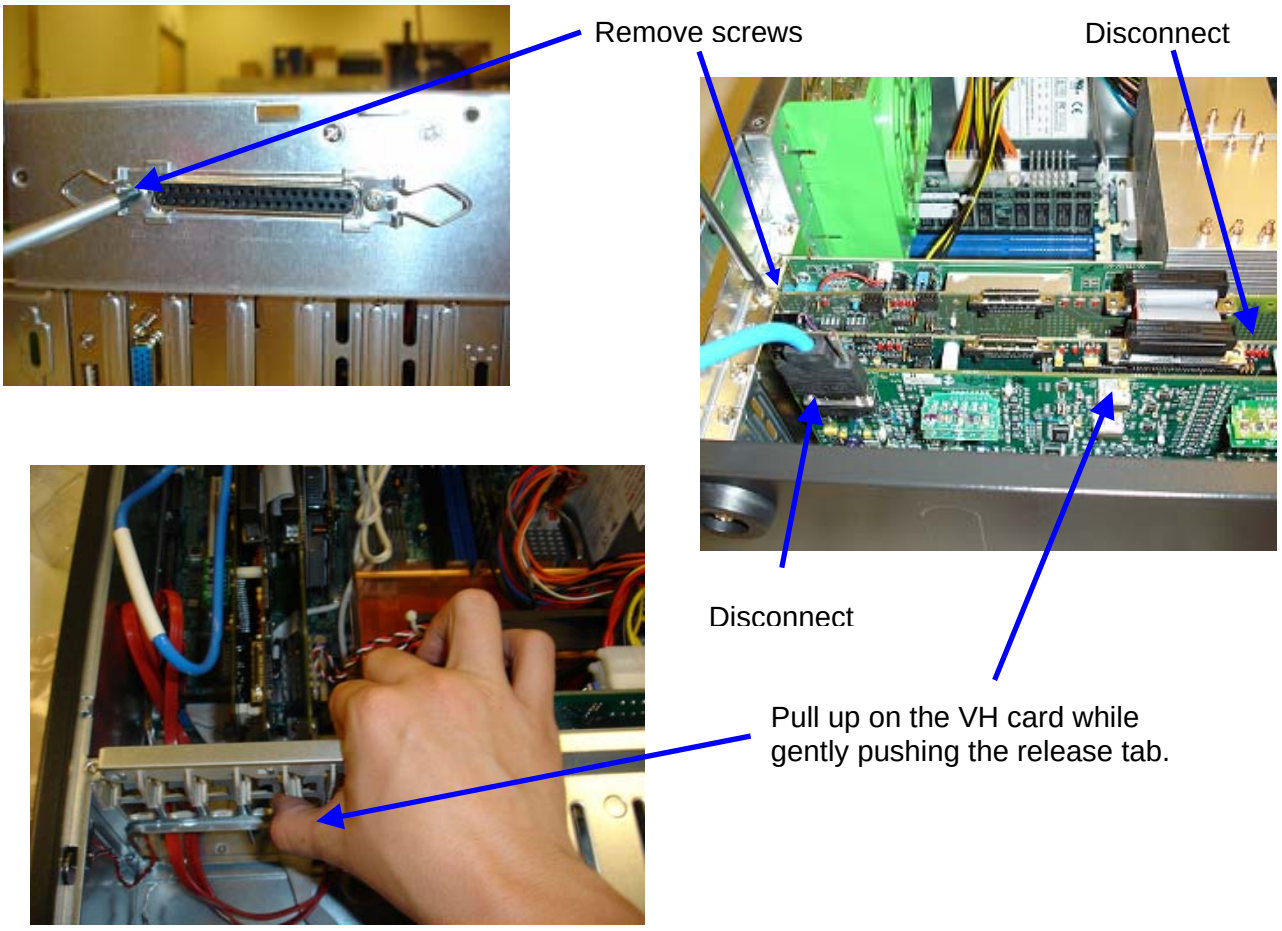


Figure 109 Removing VH Board

Installation

- Align VH Board with receiving end and gently push down in place.
- Replace the screw securing the VH card to the workstation.
- Reconnect PIM cable to VH Board.
- Replace the 2 screws that hold PIM connector onto back panel (see figure above for correct orientation).

ATX Power Supply Removal / Installation

Removal

- Perform steps outlined in section Preparation for Parts Removal / Installation on page 126.
- Remove the 3 screws that secure power supply to PC chassis.
- Unplug all cables connecting power supply to PC.

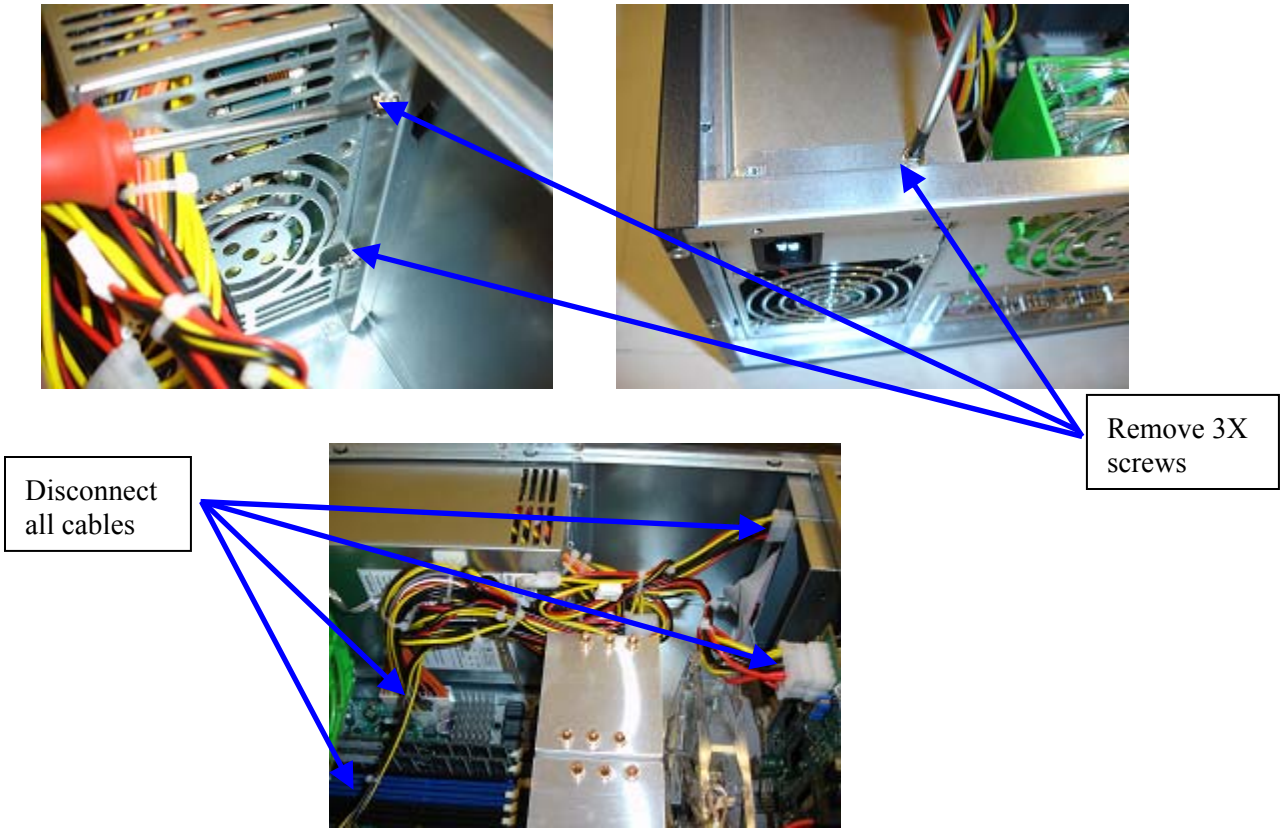


Figure 110 Removing ATX Power Supply

Installation

- Reconnect all plugs to PC in appropriate places.
- Replace 3 screws to secure to PC.

Intake Fan Removal / Installation

Removal

- Perform steps outlined in section Preparation for Parts Removal / Installation on page 126.
- Using both hands, pull up on front panel until it loosens. Move tab (see Figure 111 below) and remove front panel. Set aside.
- Remove 4 screws on front panel that hold the fan bracket to the PC.
- Free wires from cable ties. Disconnect and remove fan/bracket assembly.
- Remove 4 screws with #0 Philips head screwdriver and separate from fan from bracket.

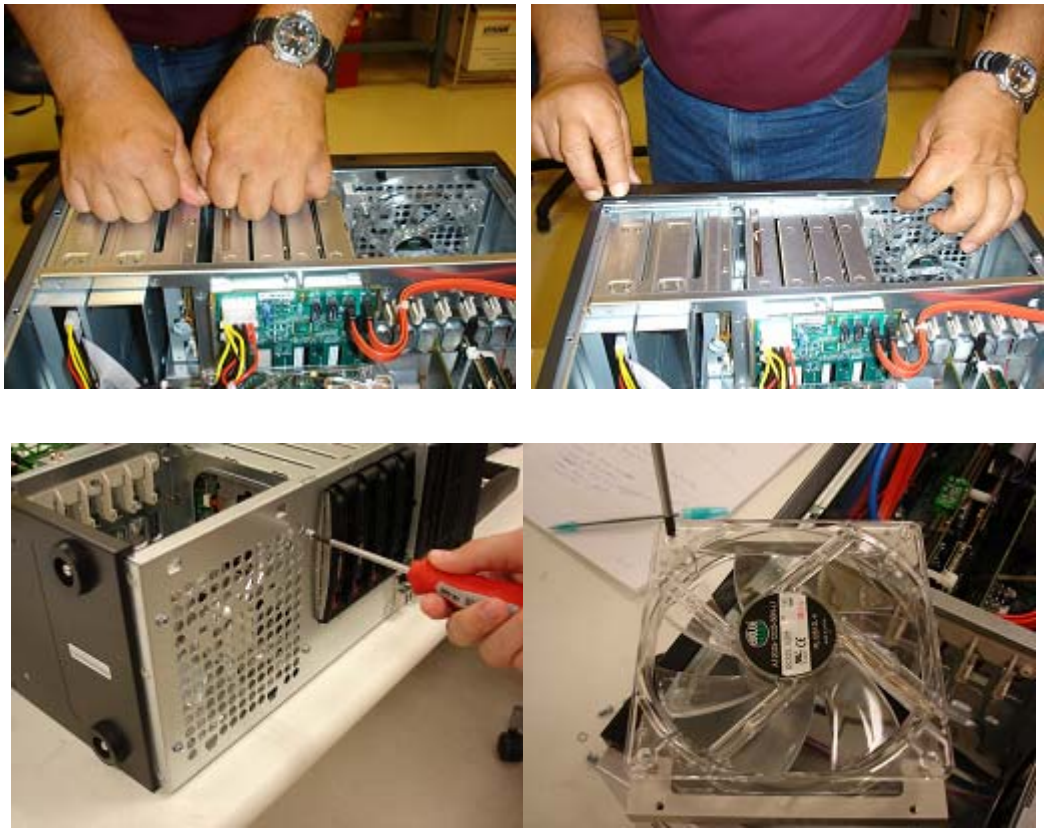


Figure 111 Removing Intake Fan

Installation

- Align bracket and replace the 4 screws that attach the fan to the fan bracket.
- Place fan into PC chassis with the serial number label facing toward the inside of the PC and replace the 4 screws to attach the bracket to the front panel.
- Reconnect the plugs into their appropriate receivers.
- Replace front panel cover.

ATX Fan Removal / Installation

Removal

- Perform steps outlined in section Preparation for Parts Removal / Installation on page 126.
- Unscrew the 2 screws that connect the fan to the PC.
- Disconnect plug.
- Separate fan from bracket by unscrewing the 2 screws with a #0 Philips screwdriver

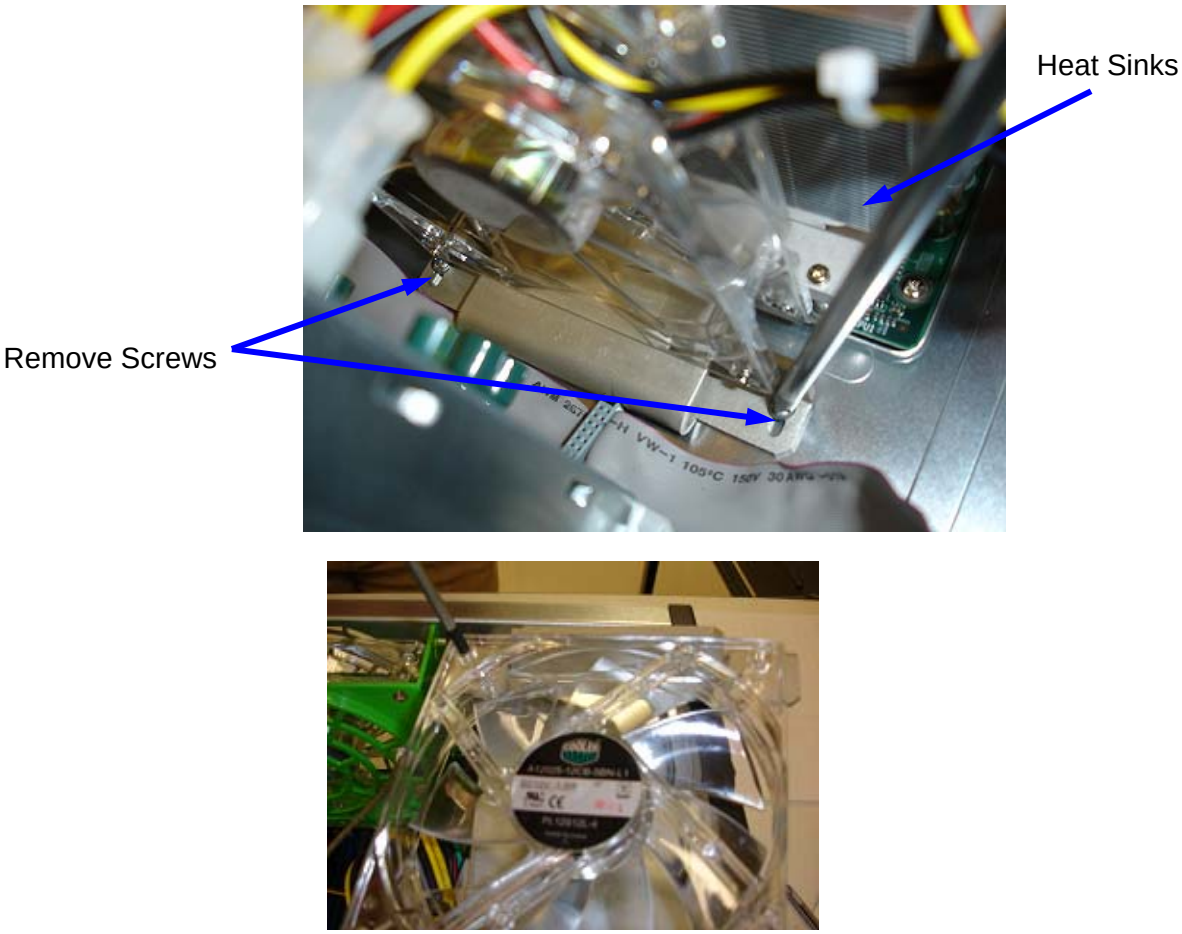


Figure 112 Removing AX Fan

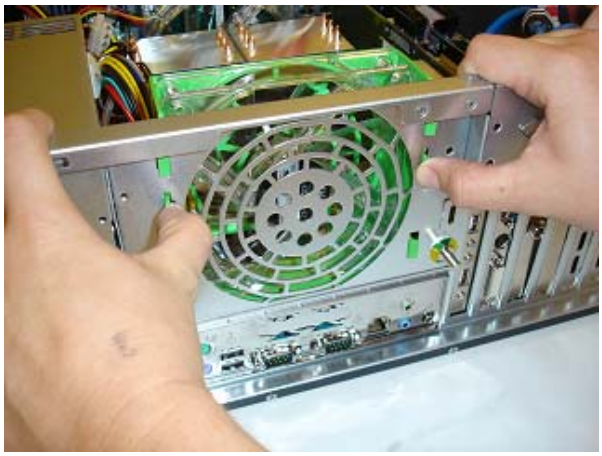
Installation

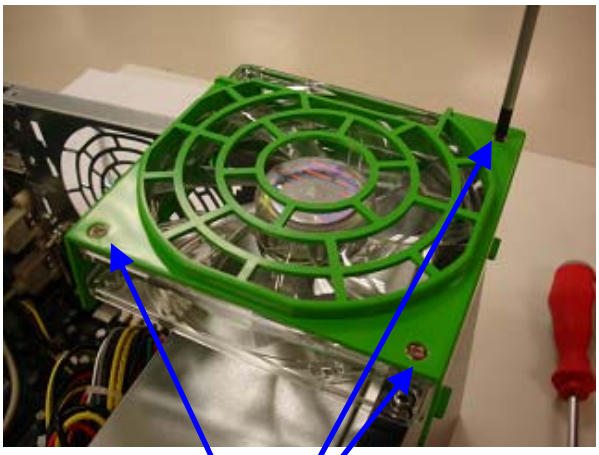
- Place fan back in bracket with the Serial number label on fan facing heat sinks and replace the 2 screws with #0 screwdriver
- Reconnect plug
- Replace the 2 screws that secure fan onto PC.

PC Fan Removal / Installation

Removal

- Perform steps outlined in section Preparation for Parts Removal / Installation on page 126.
- Open Tabs and remove fan and bracket.
- Remove the 3 screws that hold the fan to the bracket.
- Unplug cable and free cable from cable ties.
- Remove fan and connected wires.





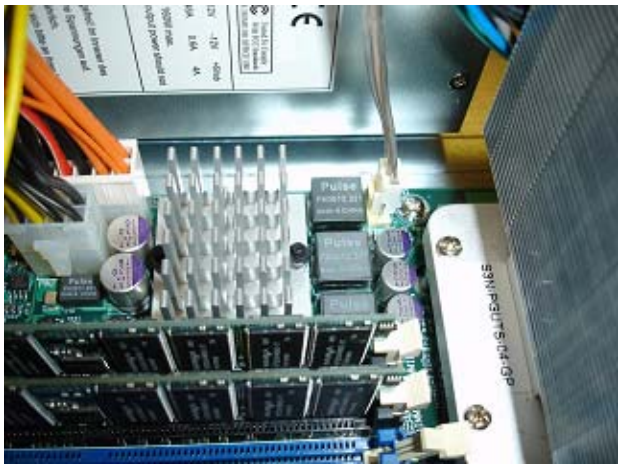


Figure 113 Removing PC Fan

Installation

- Place fan in bracket with the serial number label on fan facing out of PC and replace the 3 screws.
- Align bracket and push back into place so that tabs secure onto PC chassis.
- Organize cables with new cable ties.
- Reconnect plug.

DVD-R Drive Removal / Installation

Removal

- Perform steps outlined in section Preparation for Parts Removal / Installation on page 126.
- Remove the 4 screws holding the drive in.
- Disconnect the 2 cables attached to the drive.
- Slide drive out toward front of PC.
- Remove stopping plate from side of drive by removing 4 screws.

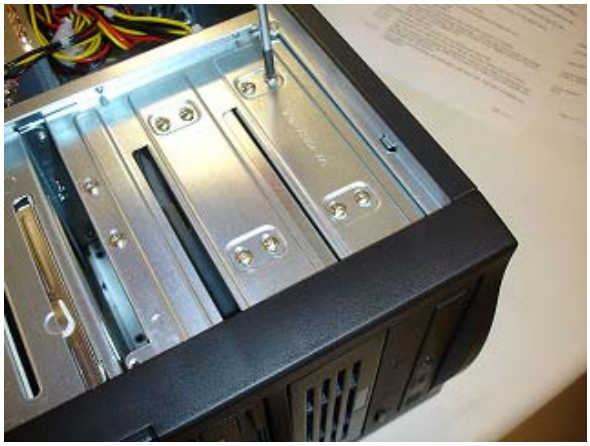


Figure 114 Removing DVD Drive

Installation

- Place stopping plate onto side of new drive by replacing the 4 screws.
- Push DVD-R drive back into drive slot on front of PC.
- Reconnect the 2 cables.
- Replace the 4 screws that secure drive into place.

Internal PIM Cable Removal / Installation

Removal

- Perform steps outlined in section Preparation for Parts Removal / Installation on page 126.
- Disconnect PIM cable from VH board.
- Remove the 2 screws connecting PIM cable to back panel. Remove old PIM cable from PC.

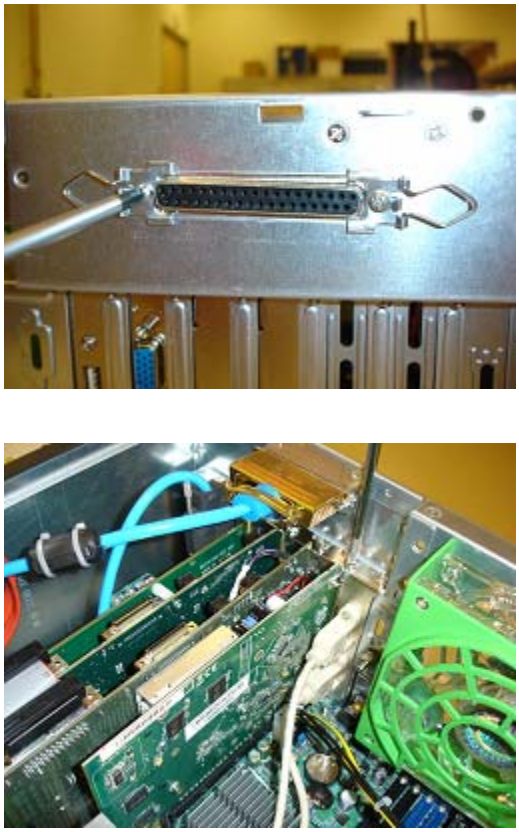


Figure 115 Removing Internal PIM Cable

Installation

- Align PIM connector into slot in back panel (see picture above) and replace the 2 screws.
- Plug the other end of PIM cable back into the VH board.

Fuses Removal / Installation

Removal

- Perform steps outlined in section Preparation for Parts Removal / Installation on page 126.
- Insert a small, flat object (flat head screwdriver, key, etc.) into the slot (see below) and pop out fuse.
- Remove fuse. NOTE: When fuse is out, the voltage may be changed between 100/120V or 240V by removing the voltage selector from beneath the fuse and turning it to desired voltage.

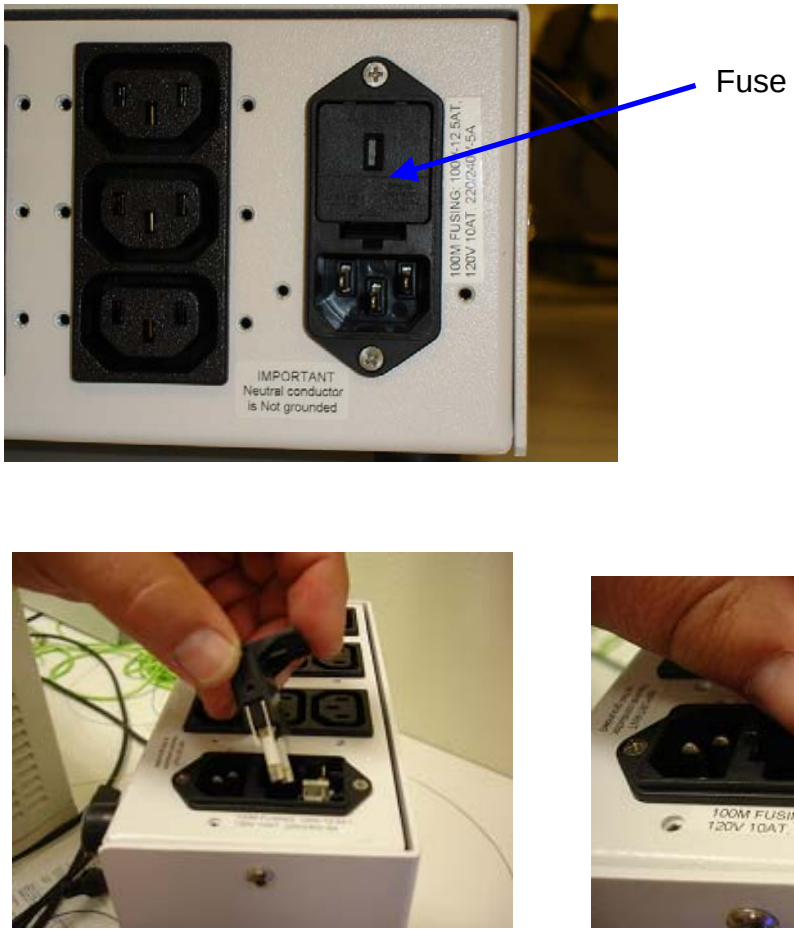


Figure 116 Removing Fuse

Installation

- Align fuse into receiver and push into place until secure.

Appendix A Field Service Mode

Field Service User Guide – Release s5i 2.2

When the s5i system is acquiring images or reviewing a case, you can bring up the Field Service dialog with **Ctrl-Alt-S**. There are six pages available: Hardware, Filter, Catheter, Software, Card Status, and Utility. You can tab through different pages in the field service dialog.

Note: Upon exiting the Field Service dialog (OK or cancel), the catheter settings will be automatically re-initialized. It is recommended that you manually disconnect and then reconnect the catheter, if any, before exiting to ensure a full re-initialization.

Hardware Page

Figure 117 shows Hardware page. There are three sections in the hardware page, the first two sections show the firmware and hardware information, including the revision information. The third section has the controls for the Test Patterns

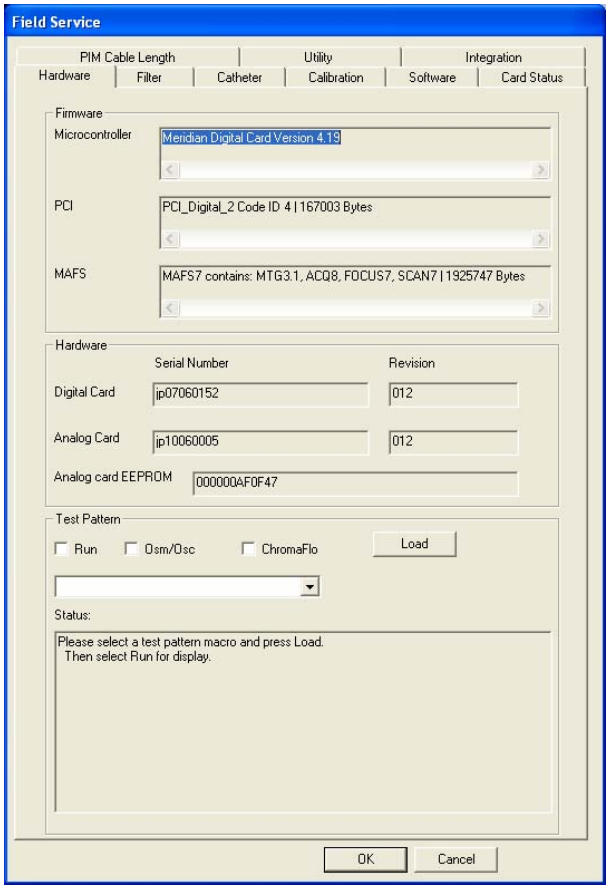


Figure 117 Hardware Page

Figure 118 shows the screen display when one test pattern is running.

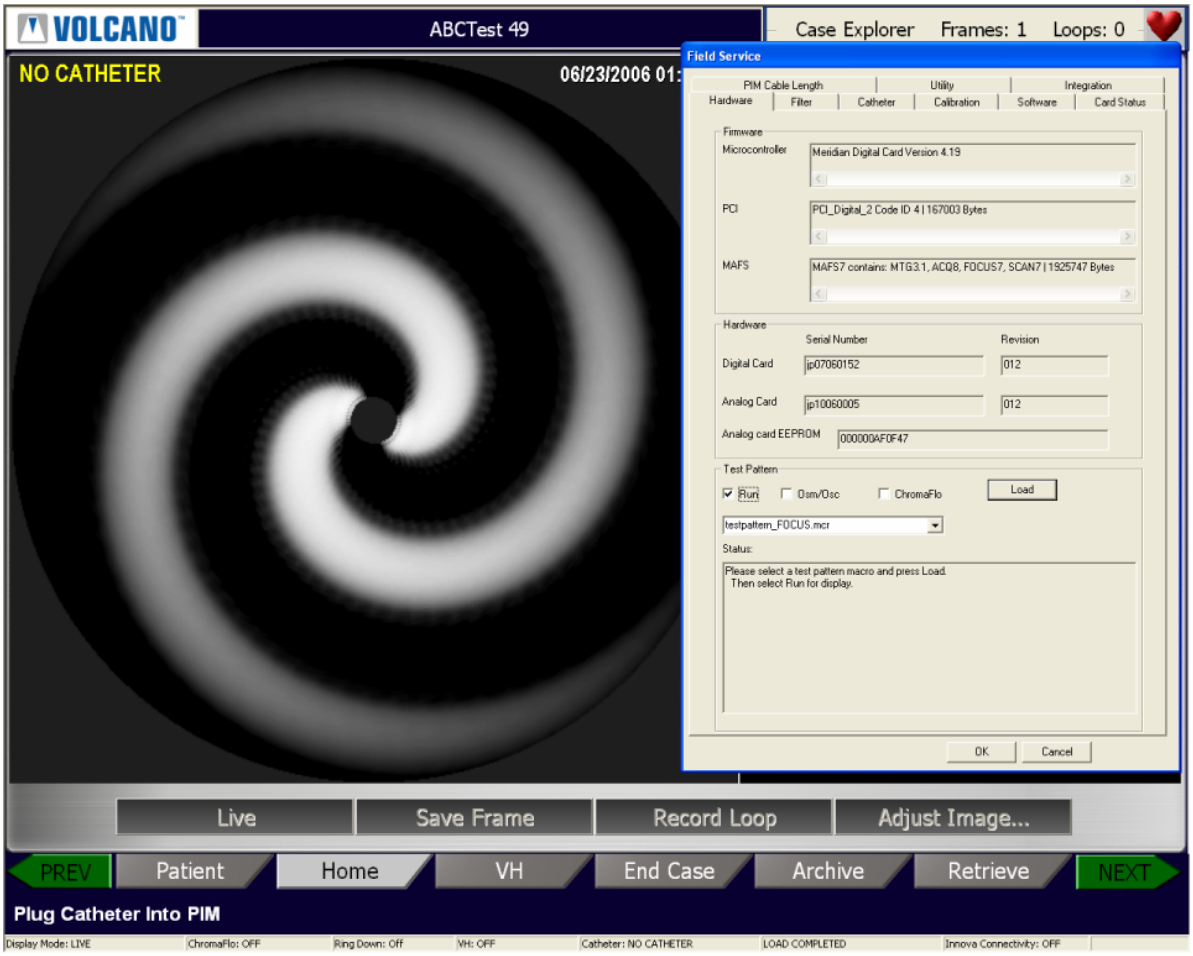


Figure 118 Running Test Pattern

There are two kinds of test patterns.

General test patterns:

1. Select a test pattern macro from the pull-down menu.
2. Make sure Osm/Osc and ChromaFlo checkboxes are not selected.
3. Press **Load** button. Other controls will be grayed out momentarily.
4. Select the **Run** checkbox to enable display on screen.

ChromaFlo test pattern (testpattern_ChromaFlo.mcr):

1. Select the ChromaFlo.mcr test pattern macro from the pull-down menu.
2. Select the **ChromaFlo** checkbox.
3. Press **Load** button. Other controls will be grayed out momentarily.
4. Select the **Run** checkbox to enable display on screen.

List of Test Patterns:

testpattern_caltone.mcr

By verifying only the following rings show up on screen, it checks that cal tone function can be enabled correctly.

[Left image] Osm/Osc should be turned off by default.

[Right image] If Osm/Osc is selected, there will be a low level shade of gray in the background.

(See also **testpattern_sequencer.mcr** below)

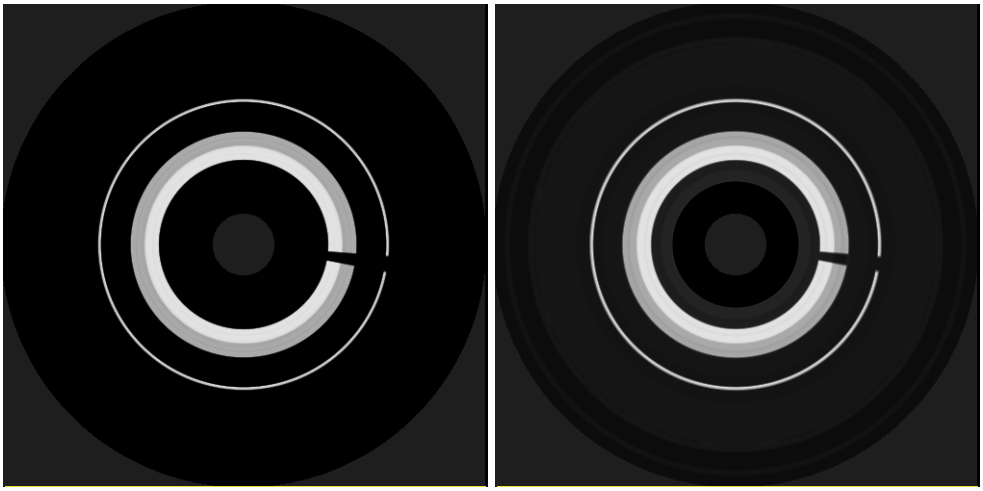


Figure 119 caltone.mcr test pattern

testpattern_ChromaFlo.mcr

ChromaFlo checkbox needs to be selected before loading this macro.

This stationary test pattern verifies that the ChromaFlo functions are working.

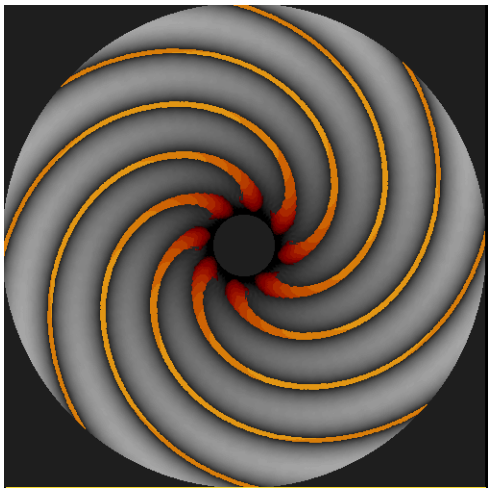


Figure 120 ChromaFlo.mcr test pattern

testpattern_deadpixels_black.mcr

testpattern_deadpixels_white.mcr

These two test patterns are used for visual detection of any dead pixel on monitor.

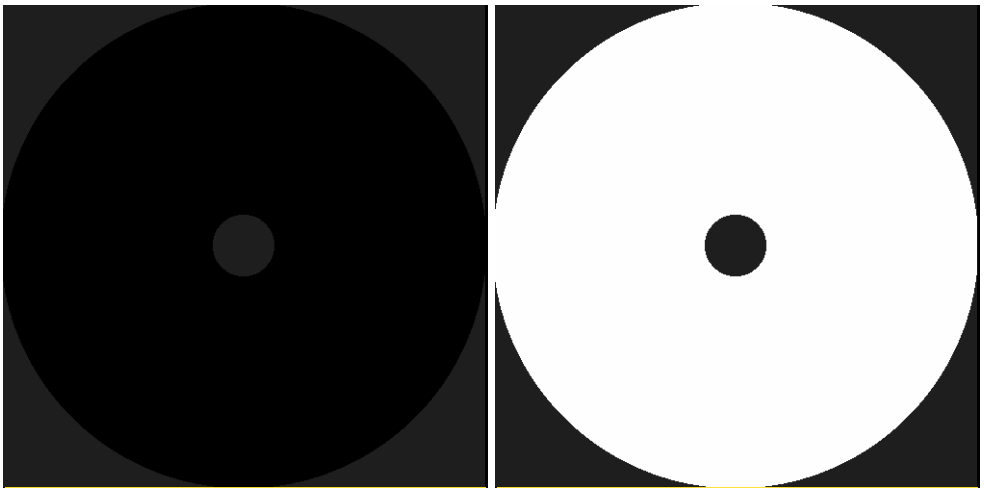


Figure 121 dead pixels test patterns

testpattern_FOCUS.mcr

This stationary test pattern uses Eagle Eye setting, and Diameter=20mm. This verifies that all operations from FOCUS FPGA and downstream of FOCUS FPGA are working for 20 MHz operation (Eagle Eye, Avanar and PV-018 catheters).

Figure 122 FOCUS.mcr test pattern

testpattern_palette.mcr

This stationary test pattern verifies that the 256 colors used in IVUS images are displayed correctly on system. (0~9: reserved overlay colors, 10: mask, 11~239: grayscale, 240~255: ChromaFlo)

Figure 123 palette.mcr test pattern

testpattern_PV82F_sim.mcr

The two images alternate at 12fps and should show a visible flicker.

This test pattern uses default PV8.2F settings, and verifies that all operations from FOCUS FPGA and downstream of FOCUS FPGA are working for 10 MHz operation.

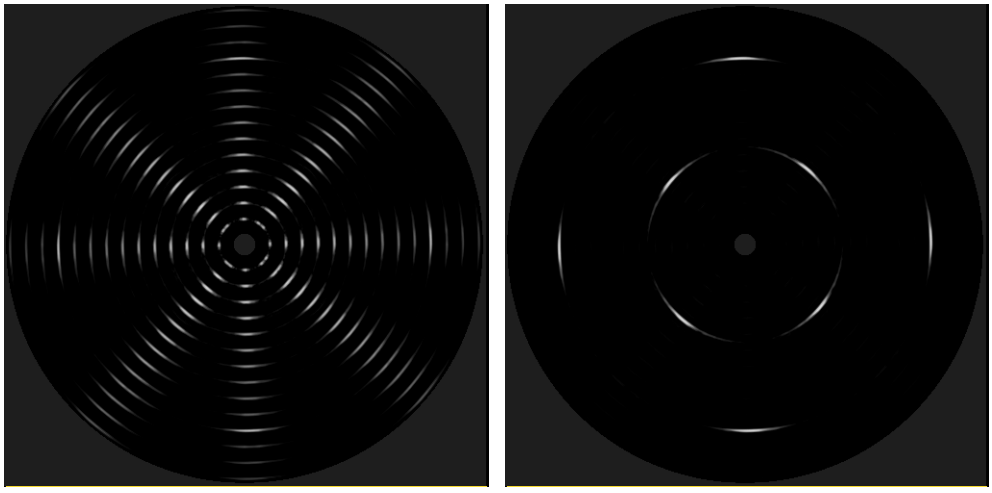


Figure 124 PV82F sim.mcr test pattern

testpattern_SCAN.mcr

The test pattern toggles at a rate of 30fps which results in the animal's eyes blinking at a rate of 15 times per second.

This test pattern can be used to detect gross frame rate degradation (frame drops) within the video subsystem.

This test pattern verifies that operations the video system downstream of the Digital card.

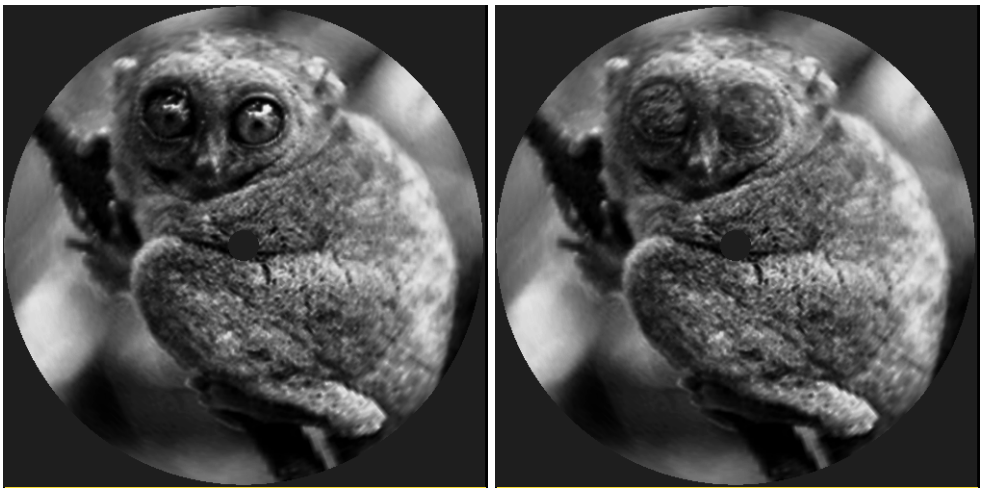


Figure 125 SCAN.mcr test pattern

testpattern_sequencer.mcr

The left image is the sequencer test pattern with the Osm/Osc switch turned off (default.)

The right image is the sequencer test pattern with the Osm/Osc switch selected. This creates an outwardly decreasing gray scale which is helpful in diagnosing video gray scale problems.

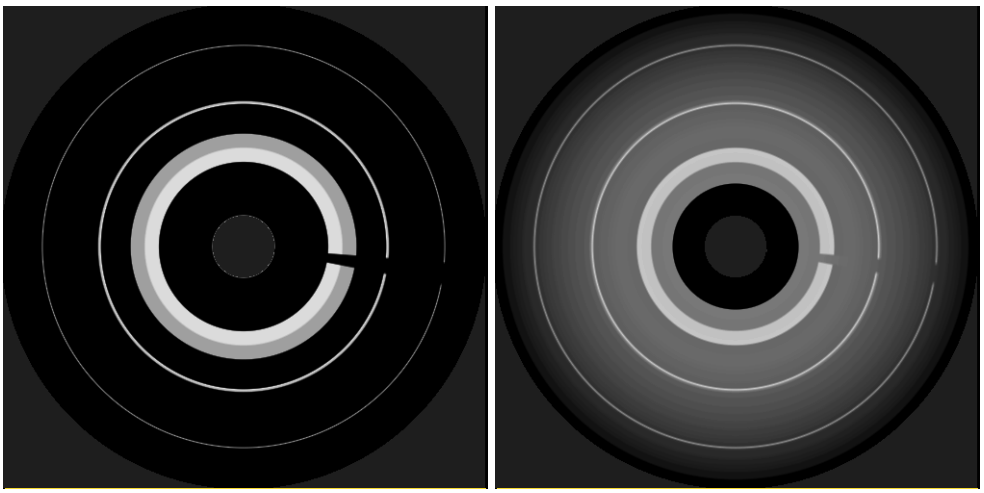


Figure 126 sequencer.mcr test pattern

testpattern_tiger.mcr

This stationary test pattern allows visual discrimination of brightness and contrast.

Figure 127 tiger.mcr test pattern

vessel_FOCUS.mcr

This stationary image is acquired off human subject in a patient study. Stent and plaque are visible in image. Data are loaded into RAWDAT buffer to test FOCUS FPGA.

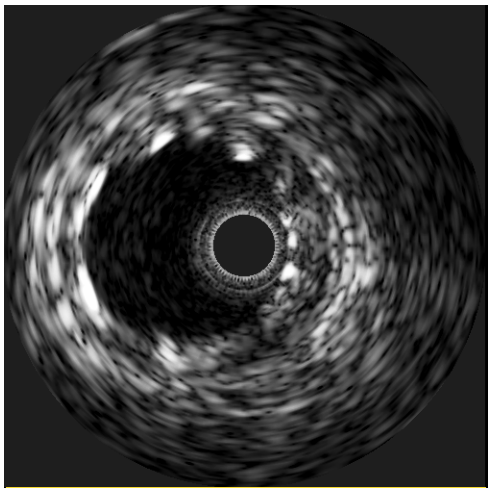


Figure 128 vessel_FOCUS.mcr

vessel_SCAN.mcr

Same as above, but with ring down subtracted, and loaded to a different stage of processing (SCINBUF).

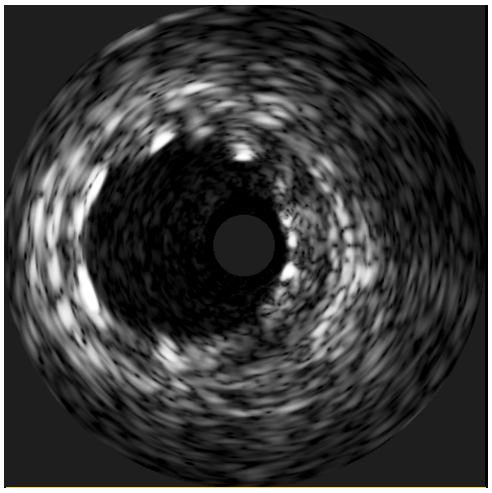


Figure 129 vessel_SCAN.mcr

Filter Page

This page shows the filter information. BP filters for normal operation will be in slots 0 (for 20 MHz) and 1 (for 10 MHz). LP filters for normal operation will be located in slots 8 (for In-Phase) and 9 (for Quadrature). Each LP filter card contains an LP filter for 20 MHz and for 10 MHz operation.

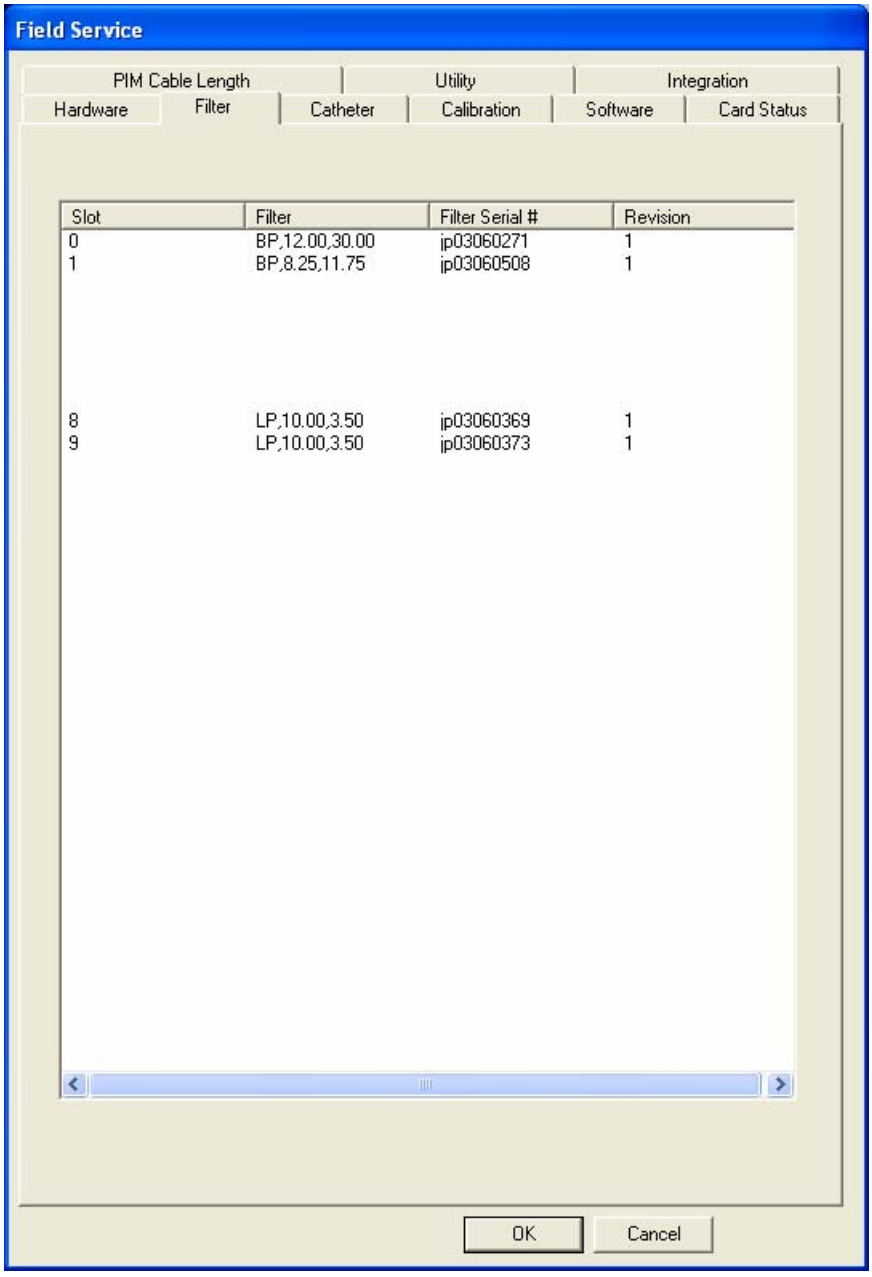


Figure 130 Filter Page

Catheter Page

This page shows the catheter information. To reconfigure the catheter, select the type of catheter, press the Run button. The Run button will be grayed out until the reconfiguration process is done. The status edit box shows whether the reconfiguration is successful or not.

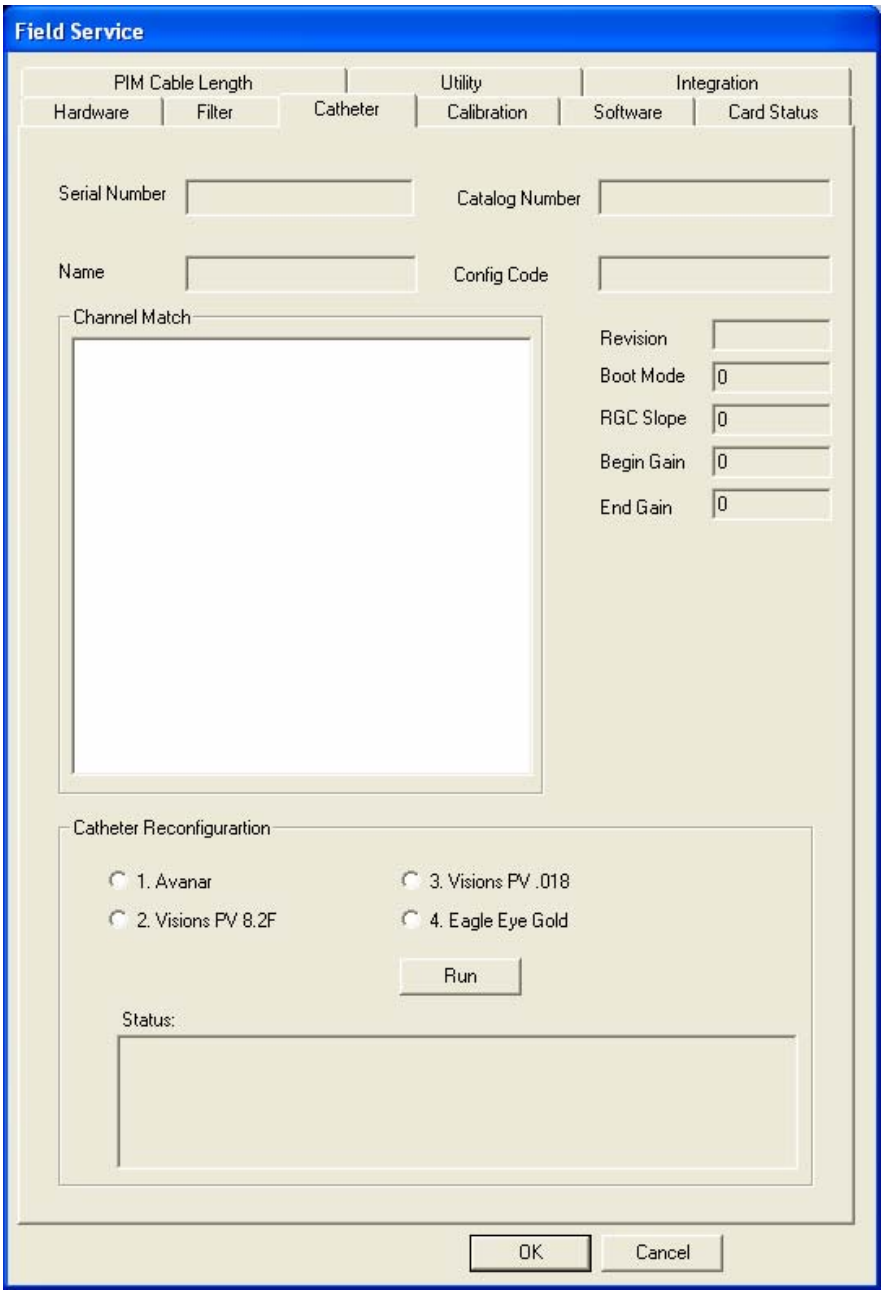


Figure 131 Catheter Page

Software Page

This page shows the revisions of the software that is available on this system, including the DLLs, and executable files. The ExecutionMgr.exe is the main application executable for s5i. In this example of Revision, 1,1,0,285, the first two parts are the release number. So this would be release 1.1. The last number is the build number (285 In this case). Note that the other executables and DLLs may not have the same release number as ExecutionMgr.exe.

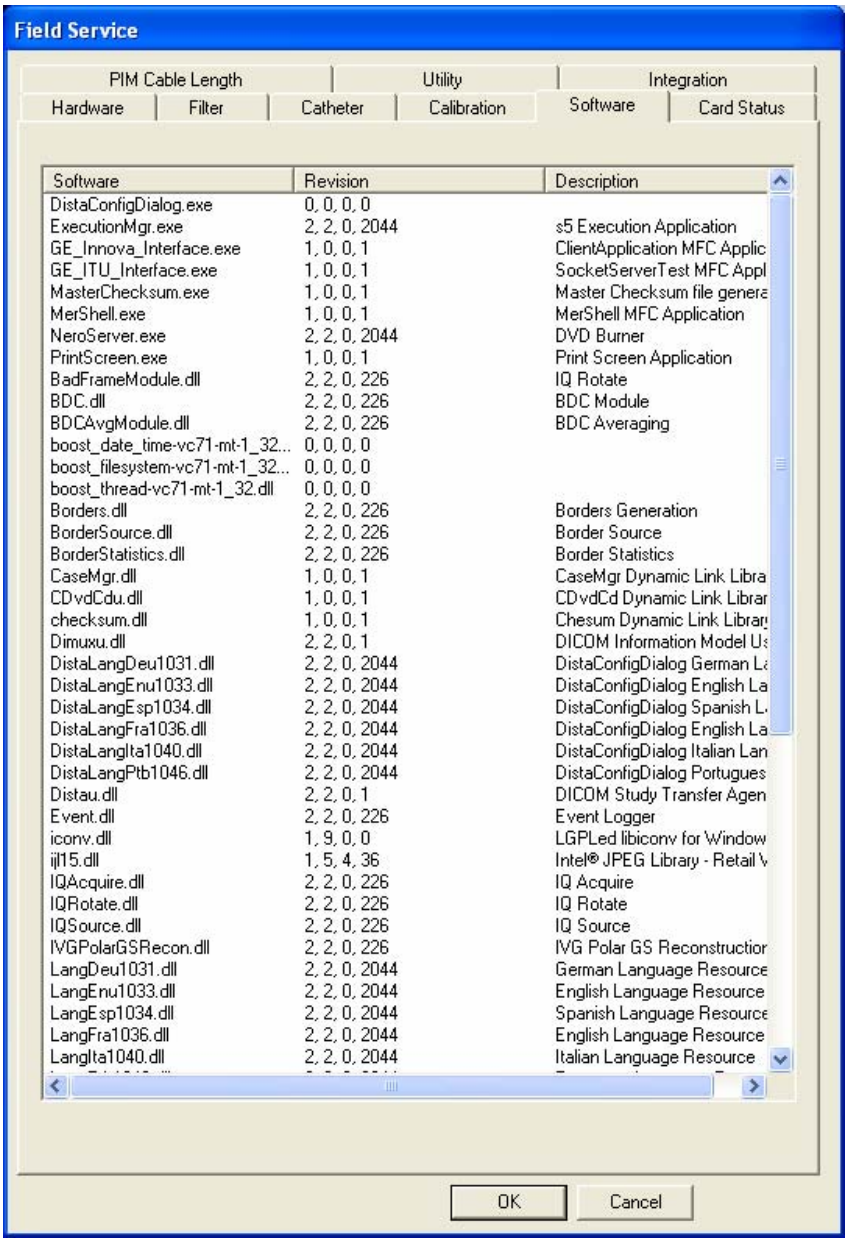

Field Service
PIM Cable Length
Utility
Integration
Hardware
Filter
Catheter
Calibration
Software
Card Status
Software
Revision
Description
DistaConfigDialog.exe 0, 0, 0, 0
ExecutionMgr.exe 2, 2, 0, 2044 s5 Execution Application
GE_Innova_Interface.exe 1, 0, 0, 1 ClientApplication MFC Applic
GE_ITU_Interface.exe 1, 0, 0, 1 SocketServerTest MFC Appl
MasterChecksum.exe 1, 0, 0, 1 Master Checksum file genera
MerShell.exe 1, 0, 0, 1 MerShell MFC Application
NeroServer.exe 2, 2, 0, 2044 DVD Burner
PrintScreen.exe 1, 0, 0, 1 Print Screen Application
BadFrameModule.dll 2, 2, 0, 226 IQ Rotate
BDC.dll 2, 2, 0, 226 BDC Module
BDCAvgModule.dll 2, 2, 0, 226 BDC Averaging
boost_date_time-vc71-mt-1_32... 0, 0, 0, 0
boost_filesystem-vc71-mt-1_32... 0, 0, 0, 0
boost_thread-vc71-mt-1_32.dll 0, 0, 0, 0
Borders.dll 2, 2, 0, 226 Borders Generation
BorderSource.dll 2, 2, 0, 226 Border Source
BorderStatistics.dll 2, 2, 0, 226 Border Statistics
CaseMgr.dll 1, 0, 0, 1 CaseMgr Dynamic Link Libra
CDvdCdu.dll 1, 0, 0, 1 CDvdCd Dynamic Link Librar
checksum.dll 1, 0, 0, 1 Chesum Dynamic Link Library
Dimuxu.dll 2, 2, 0, 1 DICOM Information Model Us
DistaLangDeu1031.dll 2, 2, 0, 2044 DistaConfigDialog German La
DistaLangEnu1033.dll 2, 2, 0, 2044 DistaConfigDialog English La
DistaLangEsp1034.dll 2, 2, 0, 2044 DistaConfigDialog Spanish L
DistaLangFra1036.dll 2, 2, 0, 2044 DistaConfigDialog English La
DistaLangIta1040.dll 2, 2, 0, 2044 DistaConfigDialog Italian Lan
DistaLangPtb1046.dll 2, 2, 0, 2044 DistaConfigDialog Portugues
Distau.dll 2, 2, 0, 1 DICOM Study Transfer Agen
Event.dll 2, 2, 0, 226 Event Logger
iconv.dll 1, 9, 0, 0 LGPLed libiconv for Window
ijl15.dll 1, 5, 4, 36 Intel® JPEG Library - Retail V
IQAcquire.dll 2, 2, 0, 226 IQ Acquire
IQRotate.dll 2, 2, 0, 226 IQ Rotate
IQSource.dll 2, 2, 0, 226 IQ Source
IVGPolarGSRecon.dll 2, 2, 0, 226 IVG Polar GS Reconstructior
LangDeu1031.dll 2, 2, 0, 2044 German Language Resource
LangEnu1033.dll 2, 2, 0, 2044 English Language Resource
LangEsp1034.dll 2, 2, 0, 2044 Spanish Language Resource
LangFra1036.dll 2, 2, 0, 2044 English Language Resource
LangIta1040.dll 2, 2, 0, 2044 Italian Language Resource
OK
Cancel

Figure 132 Software Top of the Page

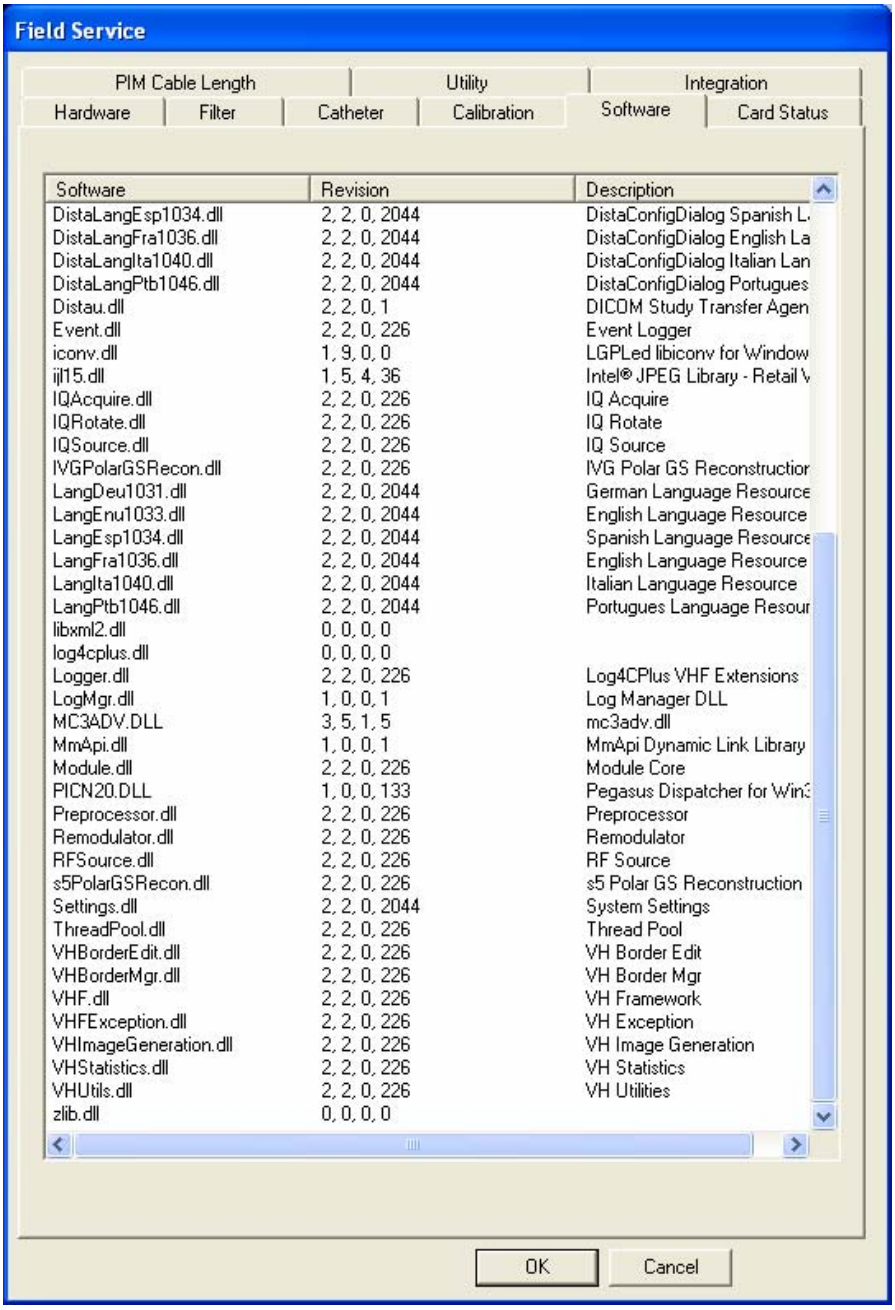

Field Service
PIM Cable Length
Utility
Integration
Hardware
Filter
Catheter
Calibration
Software
Card Status
Software
Revision
Description
DistaLangEsp1034.dll 2, 2, 0, 2044 DistaConfigDialog Spanish L
DistaLangFra1036.dll 2, 2, 0, 2044 DistaConfigDialog English La
DistaLangIta1040.dll 2, 2, 0, 2044 DistaConfigDialog Italian Lan
DistaLangPtb1046.dll 2, 2, 0, 2044 DistaConfigDialog Portugues
Distau.dll 2, 2, 0, 1 DICOM Study Transfer Agen
Event.dll 2, 2, 0, 226 Event Logger
iconv.dll 1, 9, 0, 0 LGPLed libiconv for Window
ijl15.dll 1, 5, 4, 36 Intel® JPEG Library - Retail V
IQAcquire.dll 2, 2, 0, 226 IQ Acquire
IQRotate.dll 2, 2, 0, 226 IQ Rotate
IQSource.dll 2, 2, 0, 226 IQ Source
IVGPolarGSRecon.dll 2, 2, 0, 226 IVG Polar GS Reconstructior
LangDeu1031.dll 2, 2, 0, 2044 German Language Resource
LangEnu1033.dll 2, 2, 0, 2044 English Language Resource
LangEsp1034.dll 2, 2, 0, 2044 Spanish Language Resource
LangFra1036.dll 2, 2, 0, 2044 English Language Resource
LangIta1040.dll 2, 2, 0, 2044 Italian Language Resource
LangPtb1046.dll 2, 2, 0, 2044 Portugues Language Resour
libxml2.dll 0, 0, 0, 0
log4cplus.dll 0, 0, 0, 0
Logger.dll 2, 2, 0, 226 Log4CPlus VHF Extensions
LogMgr.dll 1, 0, 0, 1 Log Manager DLL
MC3ADV.DLL 3, 5, 1, 5 mc3adv.dll
MmApi.dll 1, 0, 0, 1 MmApi Dynamic Link Library
Module.dll 2, 2, 0, 226 Module Core
PICN20.DLL 1, 0, 0, 133 Pegasus Dispatcher for Win3
Preprocessor.dll 2, 2, 0, 226 Preprocessor
Remodulator.dll 2, 2, 0, 226 Remodulator
RFSource.dll 2, 2, 0, 226 RF Source
s5PolarGSRecon.dll 2, 2, 0, 226 s5 Polar GS Reconstruction
Settings.dll 2, 2, 0, 2044 System Settings
ThreadPool.dll 2, 2, 0, 226 Thread Pool
VHBorderEdit.dll 2, 2, 0, 226 VH Border Edit
VHBorderMgr.dll 2, 2, 0, 226 VH Border Mgr
VHF.dll 2, 2, 0, 226 VH Framework
VHFException.dll 2, 2, 0, 226 VH Exception
VHImageGeneration.dll 2, 2, 0, 226 VH Image Generation
VHStatistics.dll 2, 2, 0, 226 VH Statistics
VHUtils.dll 2, 2, 0, 226 VH Utilities
zlib.dll 0, 0, 0, 0
OK
Cancel

Figure 133 Software Bottom of the Page

Card Status Page

The card status page displays the internal Voltage and temperature information. The Voltage information includes PIM Supply Voltage 5V, PSW Supply Voltage 5V, Voltage Cap+, Voltage Cap-, Supply voltage 2.5V, MC Supply Voltage 1.8V, and MC Supply Voltage 2.5V.

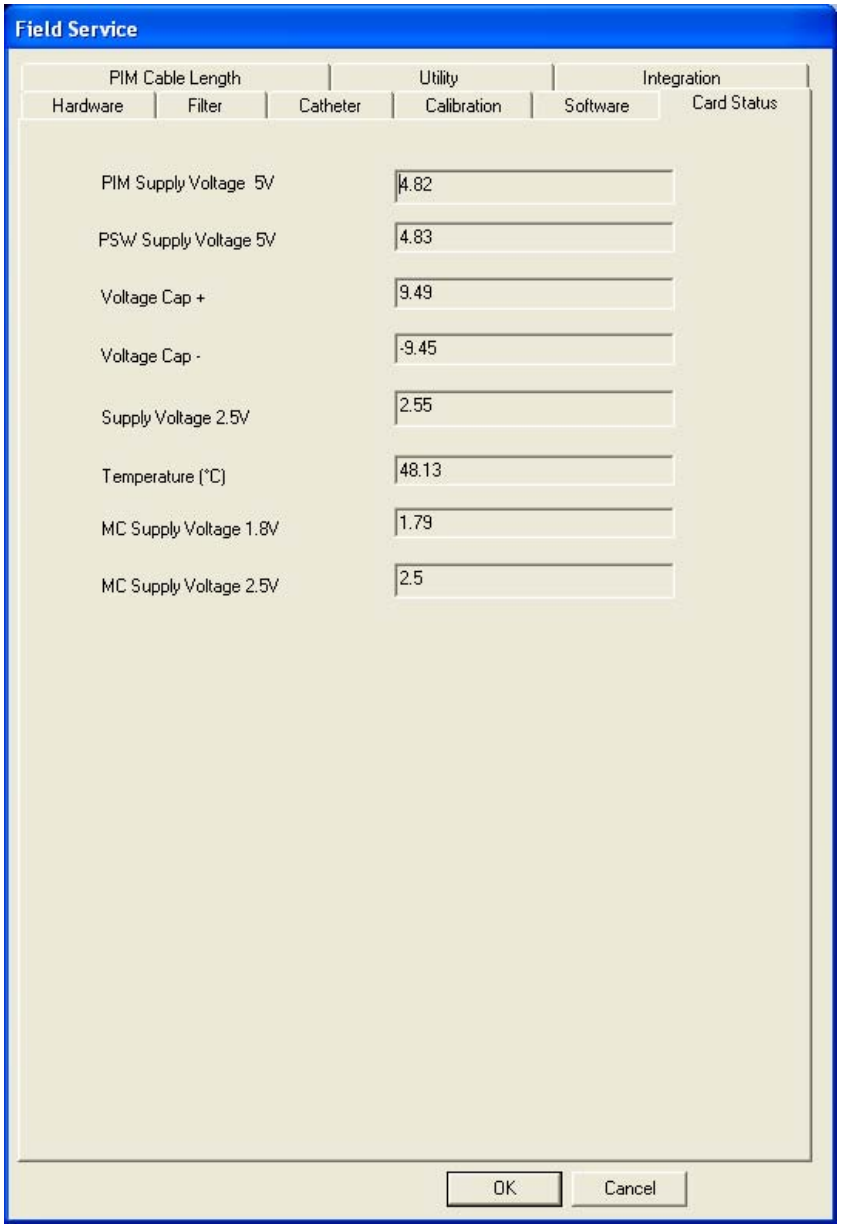


Figure 134 Card Status Page

Utility Page

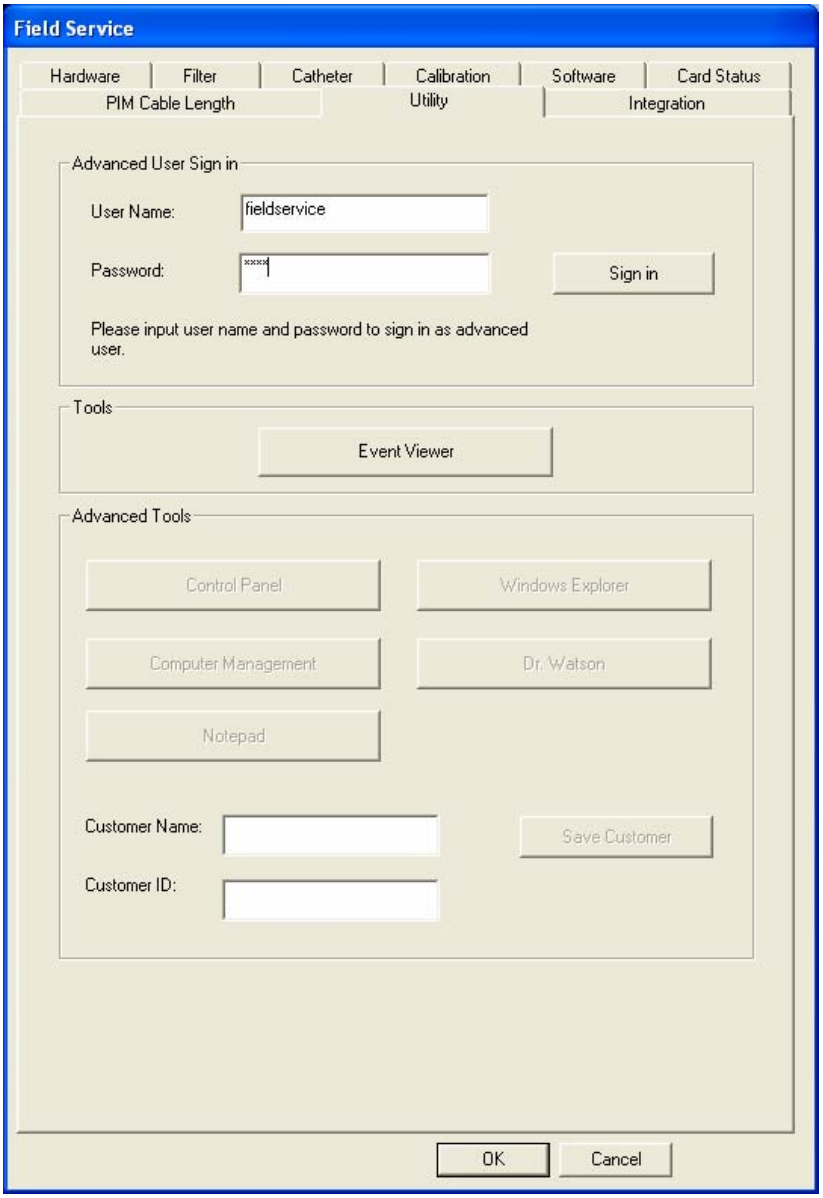


Figure 135 Utility Page Advanced User Not Signed in

The utilities page allows you to run utility tools to diagnose problems and record the problems. The utility tool includes three sections: Advanced user sign in, tools, and advanced tools.

Advanced user Field Service Sign in

CAUTION! The advanced tools are very powerful and some actions may cause the system to be set into an incorrect state, and not be recoverable. Therefore, the user name and password and should not be provided to the end user.

The Sign in user name is: **fieldservice**; password is: **eson**

After entering the user name and password do not hit the Enter button, you must instead click on the Sign in button. Hitting the Enter key aborts the Sign in process.

They are case insensitive. Once you Sign in correctly, the advanced tools are enabled.

The user name and password are hard coded in the system, and not modifiable.

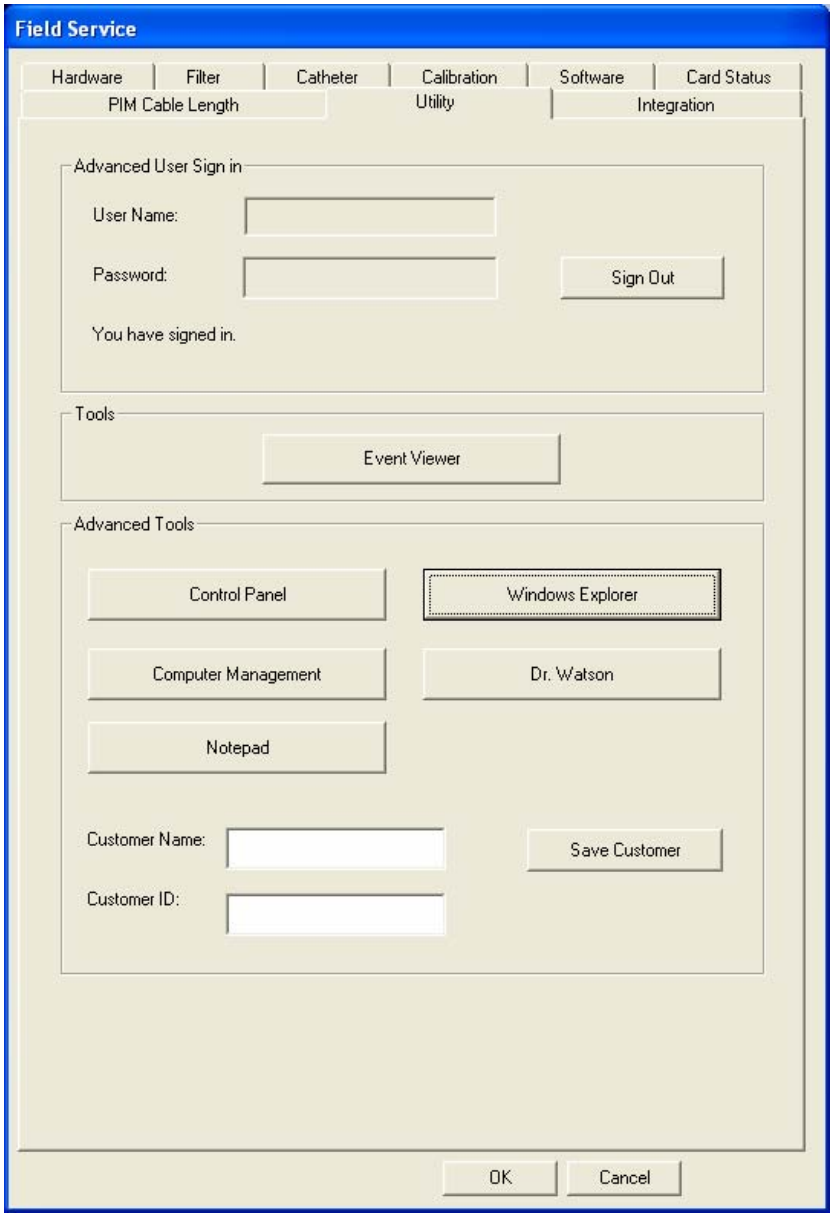


Figure 136 Utility Page Advanced User Signed in

Field Service Login at Startup

Alternatively, you can sign into the advanced service menu prior to the system completing initialization. (i.e. Before the s5i IVUS application loads.) This may be helpful for troubleshooting operating system anomalous behavior.

As the system boots up, watch for the Volcano logo and start tapping the F8 key on the keyboard or the Settings button on the console. Do not start before the Volcano Logo appears. When the login screen appears, enter the username and password and click OK. (see Figure 137 System Access at Startup below).

Input the User name: **fieldservice** Password: **eson** (case insensitive)

This opens Windows Explorer. Navigate to the C:\FieldService folder. There are three files there:

- Shortcut to Tools.exe

  These tools provide access to Deep Freeze, the Task Manager and the Windows Task bar and Desktop.

- Shortcut to System

  A means to start the s5i application

- Shut_down.exe

  A means to power down the CPU from the keyboard.

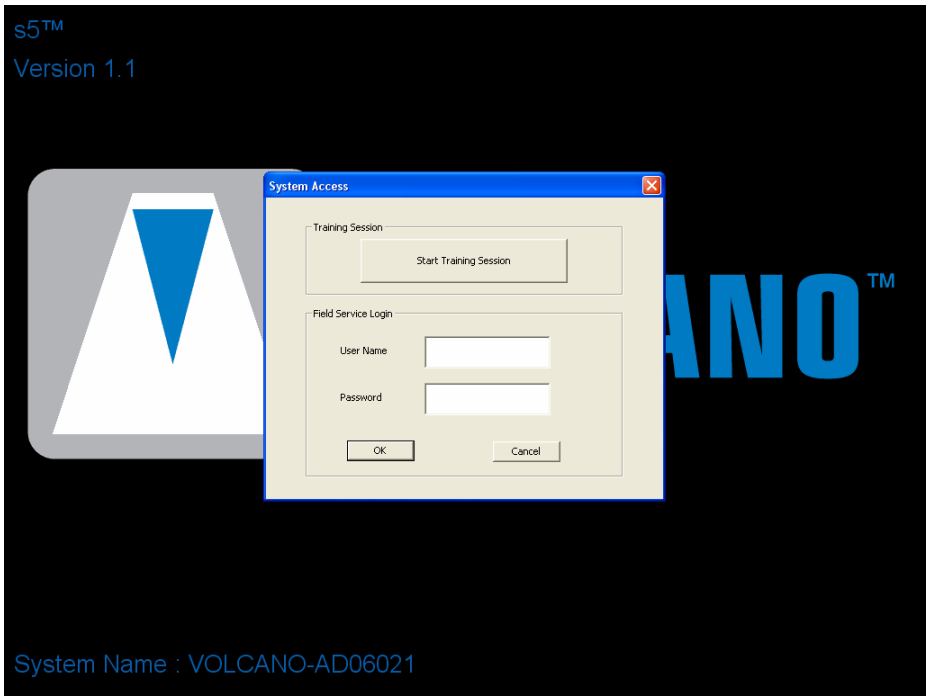


Figure 137 System Access at Startup

Advanced User Service Menu

Once you Sign in, you can use all the advanced tools and functions in all the pages of the field service dialog. You will be logged out automatically when the field service mode is

deactivated by clicking Cancel. When using the advanced tools a single click is required to launch tools from the advanced menu. A double click may cause the application to lose focus. If this occurs, use the **Alt Tab** controls to regain the appropriate focus.

Tools section

Event Viewer – browse event logs, and check what happened to the system.

Advanced tools

Control Panel – manage the setup of the system, including hardware and software. The printer setup is here.

Computer Management –manage local and remote computers. It includes system tools and storage subsection.

The system tool subsection includes:

- Event viewer
- Share folders
- Local users and groups
- Performance logs and alerts
- Disk manager

The storage subsection includes:

- Removable Storage
- Disk defragmenter
- Disk management

Dr. Watson: Dr. Watson detects information about system and program failures and records the information in a log file in the event of a program error.

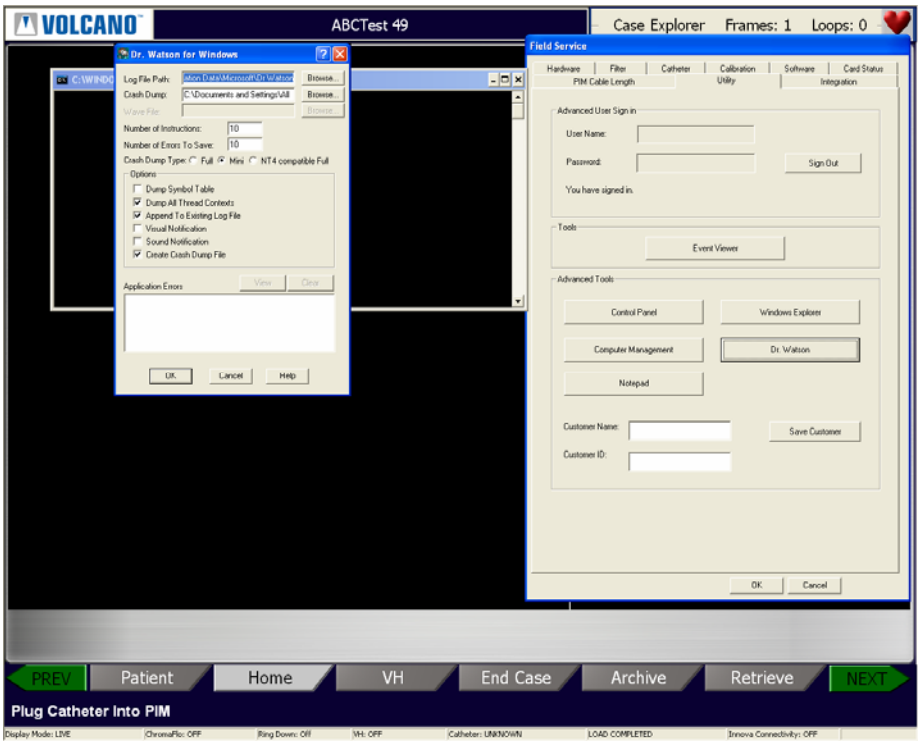


Figure 138 Field Service -> Dr. Watson

Windows Explorer: A powerful file management tool.

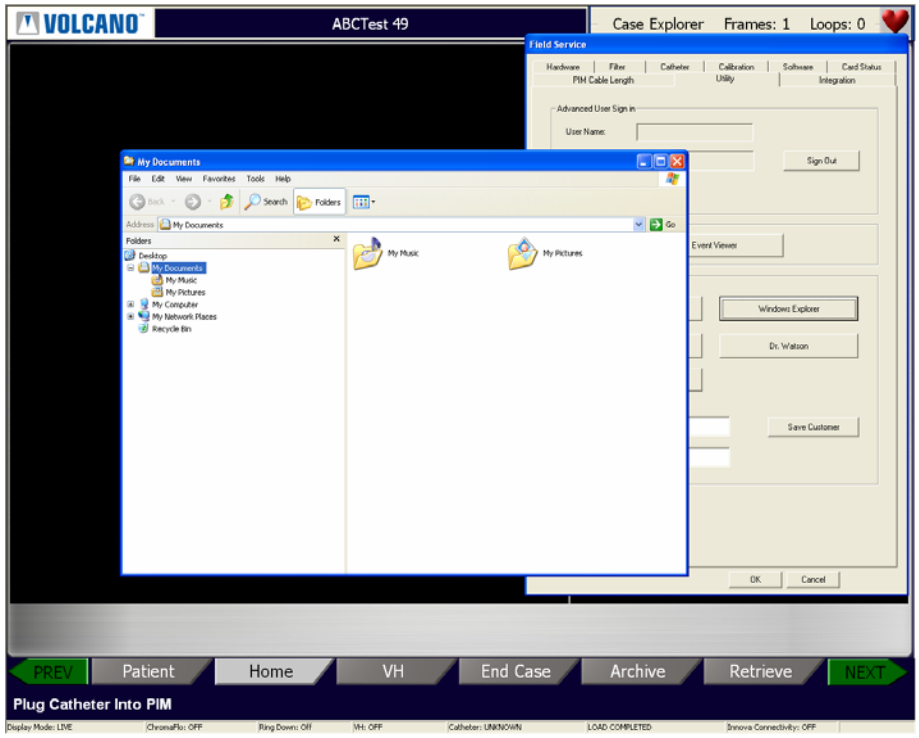


Figure 139 Field Service -> Windows Explorer

Control Panel: Provides access to the Windows Control Panel.

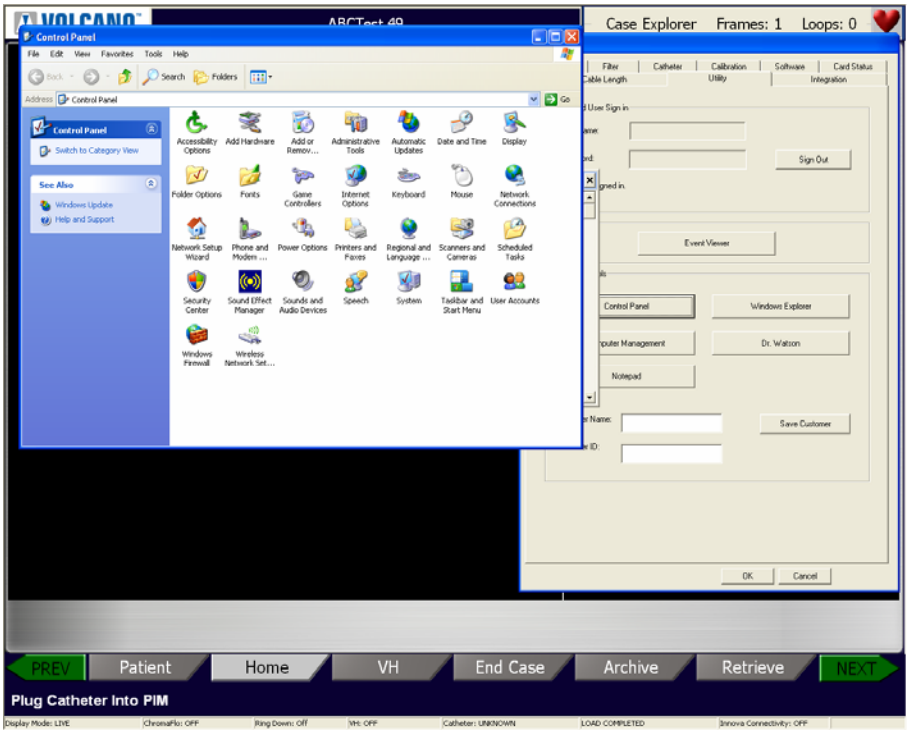


Figure 140 Field Service -> Control Panel

Computer Management: Provides access to Windows Computer Management.

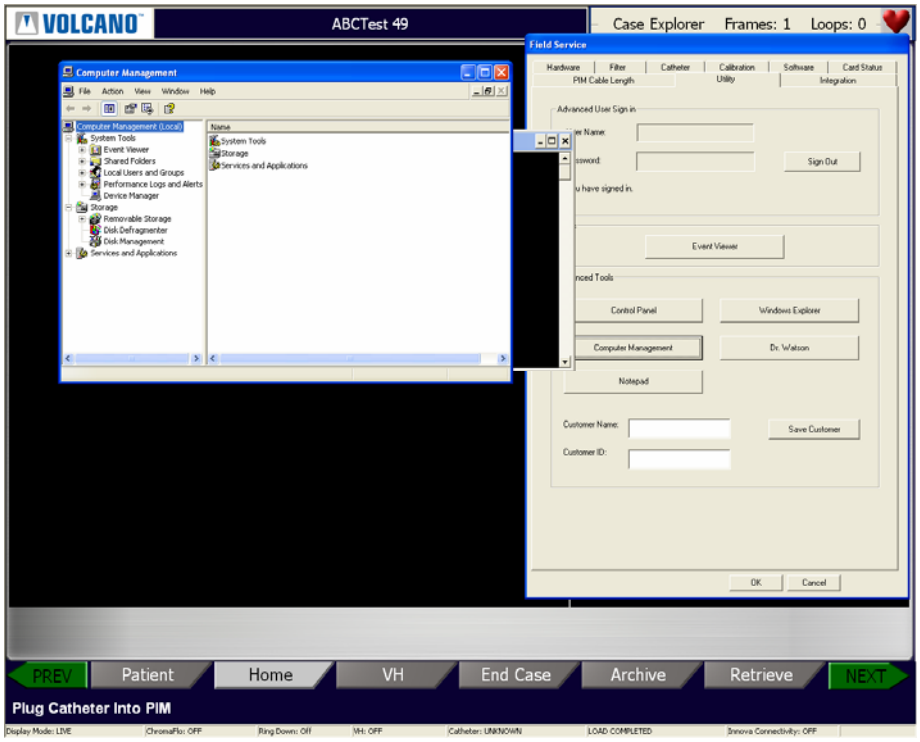


Figure 141 Field Service -> Computer Management

Notepad: Allows access to Notepad to create, edit and save *.txt files.

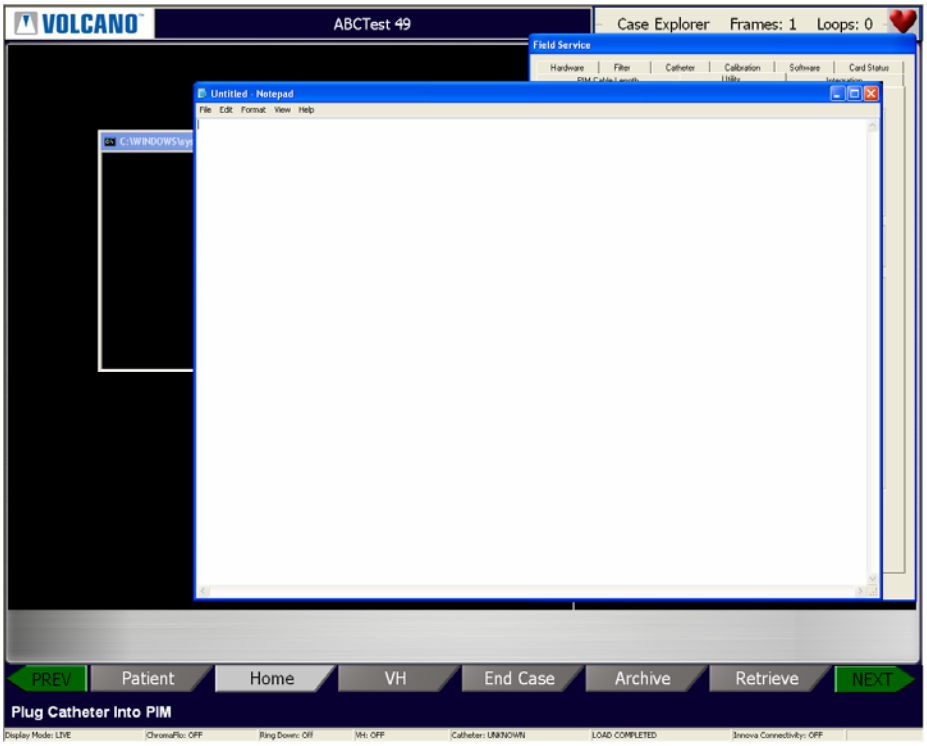


Figure 142 Field Service -> NotePad

Field Service Administrative Tools

Using Tools.exe

This application gives field service the option to shut down the system gracefully, turn DeepFreeze on and off, and to execute system commands in DOS mode (at the Command Prompt).

DeepFreeze protects the integrity of the system by write protecting selected directories and the Windows Registry. DeepFreeze must be turned off to change any feature, add printer drivers, and install software. With DeepFreeze 'ON' the user is allowed to complete destructive tasks but a simple reboot of the system will restore any seemingly changed or deleted files. Thus a virus attack or an attempt at erasing documents cannot happen without first shutting DeepFreeze down.

Accessing the Tools.exe application:

To access the Tools.exe application log into the Advanced user Field Service Sign in (see Advanced user Field Service Sign in on page 151). Open Windows Explorer by clicking on the Windows Explore button within the advanced user's service menu. Using Windows explorer navigate to the Tools.exe application at C:/FieldService.

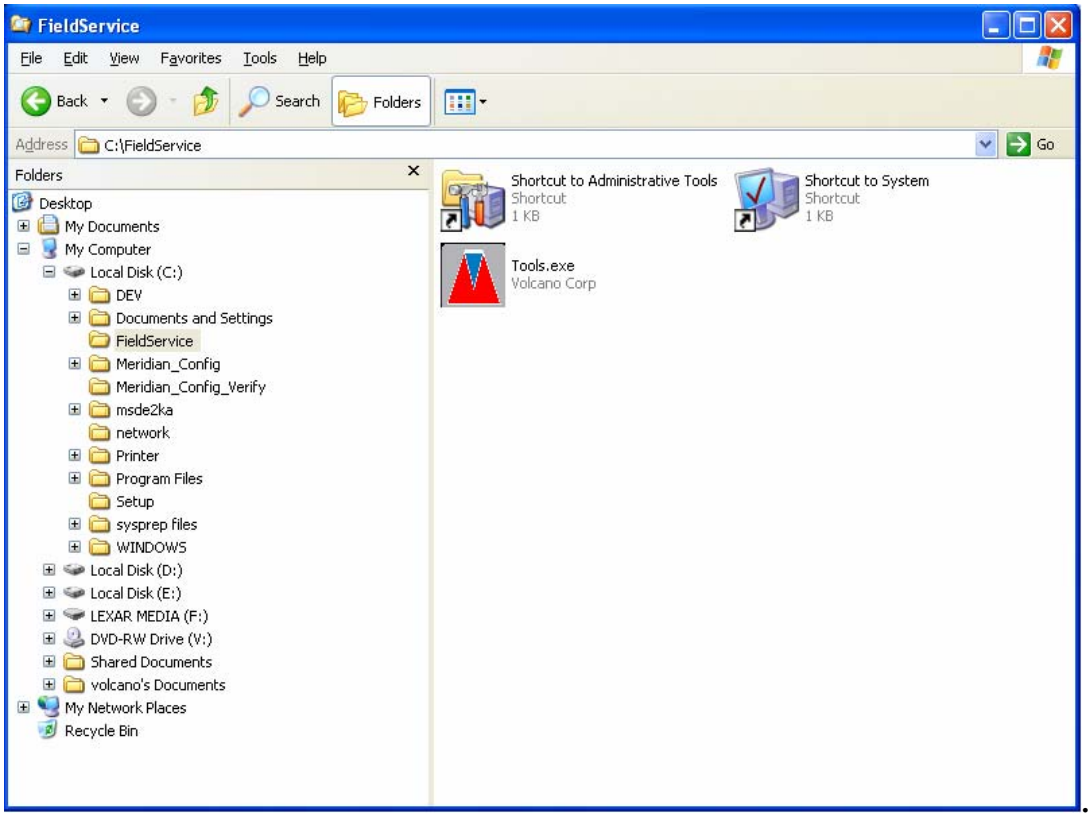


Figure 143 Navigating to the Deep Freeze application

Double clicking on the Tools.exe icon will launch the application

Figure 144 Tools.exe application control console

DF OFF

This button turns deep freeze off and restarts the computer so that the thawed mode can take effect. In the thawed mode permenent changes can be made to the hard drive regions normally protected by Deep Freeze.

DF ON

If Deep Freeze is in the thawed mode at an explorer shell, this button will turn on Deep Freeze, change shell back to Mershell, and restart the system. The Mershell is the user interface that replaces the standard Windows Explorer shell. The Mershell allows oversight of keystrokes and Control codes (e.g. Control-Alternate-Delete is prevented from operating), to prevent user access to the Windows and s5i operating system.

DF Status

This button will show the current status of Deep Freeze.

CMD

This button will open the Dos Command window**.**

Turn Off

This button will shut down the computer. If the s5i application is running, click **end now** to terminate the application.

Restart.

If Deep Freeze is turned off, this button boots the computer back to Windows Explorer mode and asks for a login and pass word as Window is starts.

If the Deep Freeze is on, this button simply restarts the computer.

Task Manager

This button will open the Windows Task Manager.

Task Bar

This button will open the Windows Task Bar.

DVD-ROM Setup:

This control is used to configuring an external USB 2.0 DVD writer.

PIM Setup:

This control is an alternative method to set the PIM cable length. This provides three PIM cable length options:

1. 30 meters,
2. 5 meters, and
3. Unknown.

Note: If the system is set to unknown the application will throw an exception error at boot.

Event File – Copy Procedure

This procedure is used to copy system information or error logs located in the event files. Event file error logs are used by Volcano software development team to diagnose software anomalous behavior. When a software failure is suspected, the event logs should be copied from the customer system and mailed to Volcano service department.

1. Log into the system as field service. See Field Service Login at Startup on page 153.
2. Insert a blank CD or DVD into the DVD drive.
3. On the Utility page of the service menu single click on **Event Viewer**.
4. In the Event Viewer window double click on **Volcano**.

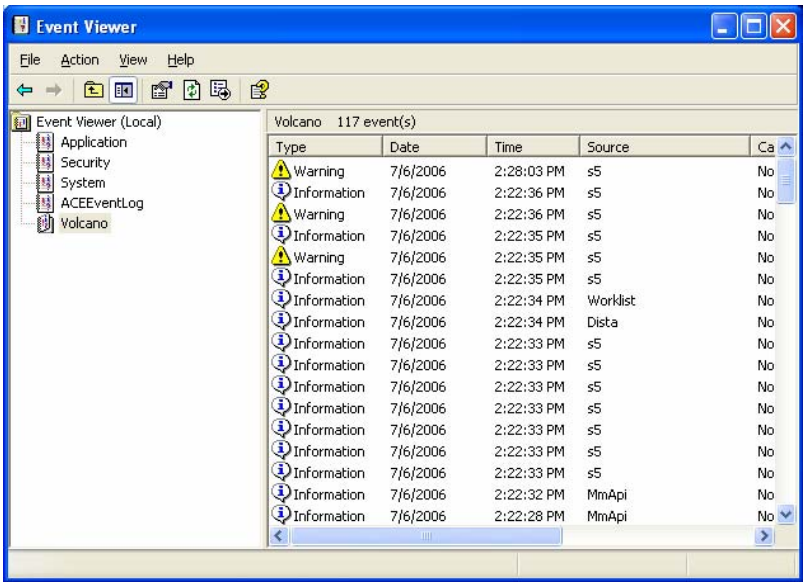

Event Viewer
File Action View Help
Event Viewer (Local)
Application
Security
System
ACEEventLog
Volcano
Volcano 117 event(s)
Type Date Time Source Ca
Warning 7/6/2006 2:28:03 PM s5 No
Information 7/6/2006 2:22:36 PM s5 No
Warning 7/6/2006 2:22:36 PM s5 No
Information 7/6/2006 2:22:35 PM s5 No
Warning 7/6/2006 2:22:35 PM s5 No
Information 7/6/2006 2:22:35 PM s5 No
Information 7/6/2006 2:22:34 PM Worklist No
Information 7/6/2006 2:22:34 PM Dista No
Information 7/6/2006 2:22:33 PM s5 No
Information 7/6/2006 2:22:33 PM s5 No
Information 7/6/2006 2:22:33 PM s5 No
Information 7/6/2006 2:22:33 PM s5 No
Information 7/6/2006 2:22:33 PM s5 No
Information 7/6/2006 2:22:33 PM s5 No
Information 7/6/2006 2:22:33 PM s5 No
Information 7/6/2006 2:22:33 PM s5 No
Information 7/6/2006 2:22:32 PM MmApi No
Information 7/6/2006 2:22:28 PM MmApi No

Figure 145 Event Viewer

5. In the Event Viewer window select the **Action** button and highlight **Save Log File As…**
6. Save the log file in the My Documents folder as "s5i event log serial number 068XXXXX001.evt where XXXXX corresponds to the system's unique serial number.
7. Close the Event Viewer.
8. On the Utility page of the service menu single click on Windows Explorer.
9. Navigate to the following location: C:\Program Files\Ahead\Nero StartSmart

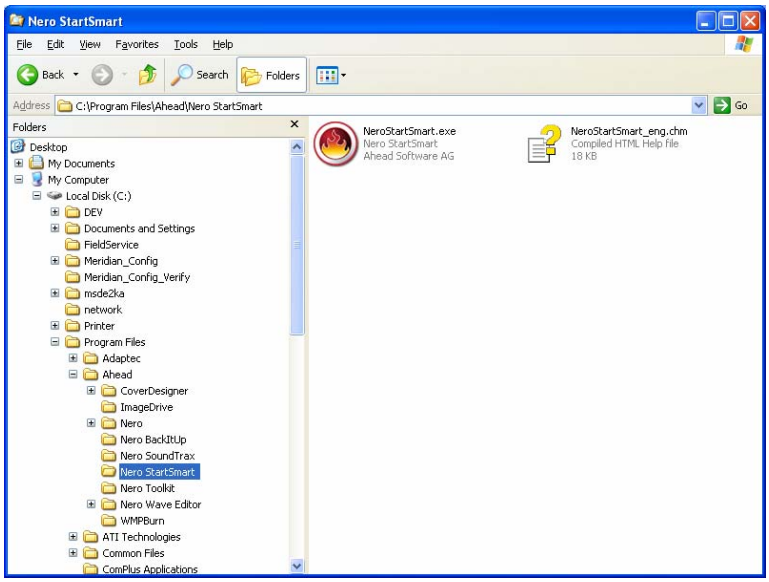


Figure 146 NeroStartSmart.exe

10. Double click on the NeroStartSmart.exe file.
11. Select **Make Data CD** or **Make Data DVD** depending on available media.

Figure 147 Nero Application

12. In the Select Files and Folders window single click on **Add** and add the event log to the disc contents by double clicking on the event log previously saved in the My Documents folder.
13. Close the Select Files and Folders window by single clicking on **Finished.**

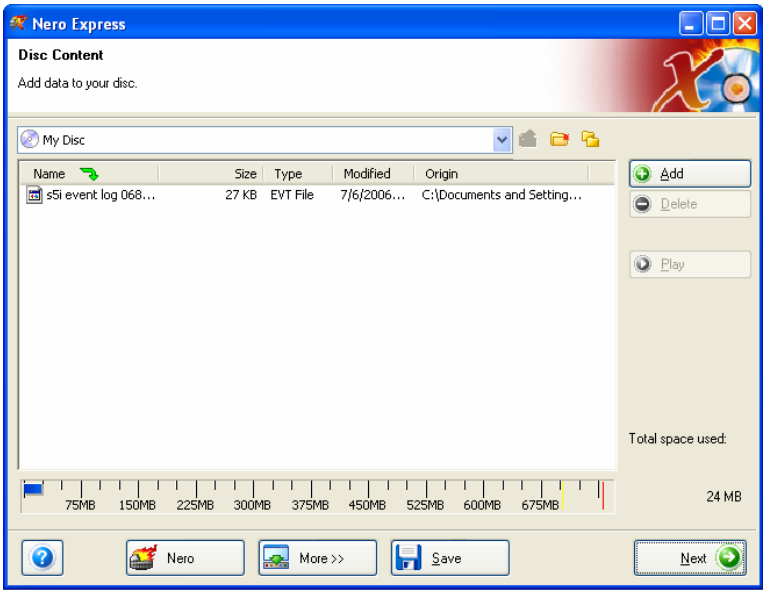


Figure 148 Nero Express

14. In the Nero Express Window select **Next**.
15. In the Nero Express window select Burn.
16. Wait for disk write to complete.
17. Eject the CD or DVD and send it to Volcano Field Service at:

Volcano Corporation
2870 Kilgore Road
Rancho Cordova, CA 95670 USA
Atten: Field Service s5i Event Log

GE INNOVA Integration

This section contains technical information on configuring the s5i to communicate with the GE Innova system. When enabled, the s5i can be remotely controlled via the Innova Integrated Touch screen Unit (ITU.) When the Innova IVUS interface is enabled, the s5i can automatically import patient demographic data from the Innova system.

Loading ITU Software for s5i connectivity

In order to enable the ITU connectivity feature, the ITU software must be updated using the ITU software distributed on the s5i service disk. Refer to GE service note sn4620 INNOVA 2100IG TSM3 UPGRADE PROCEDURE.pdf or CNF0091 – Intelligent Touch Screen Unit (ITU) configuration for installation instructions.

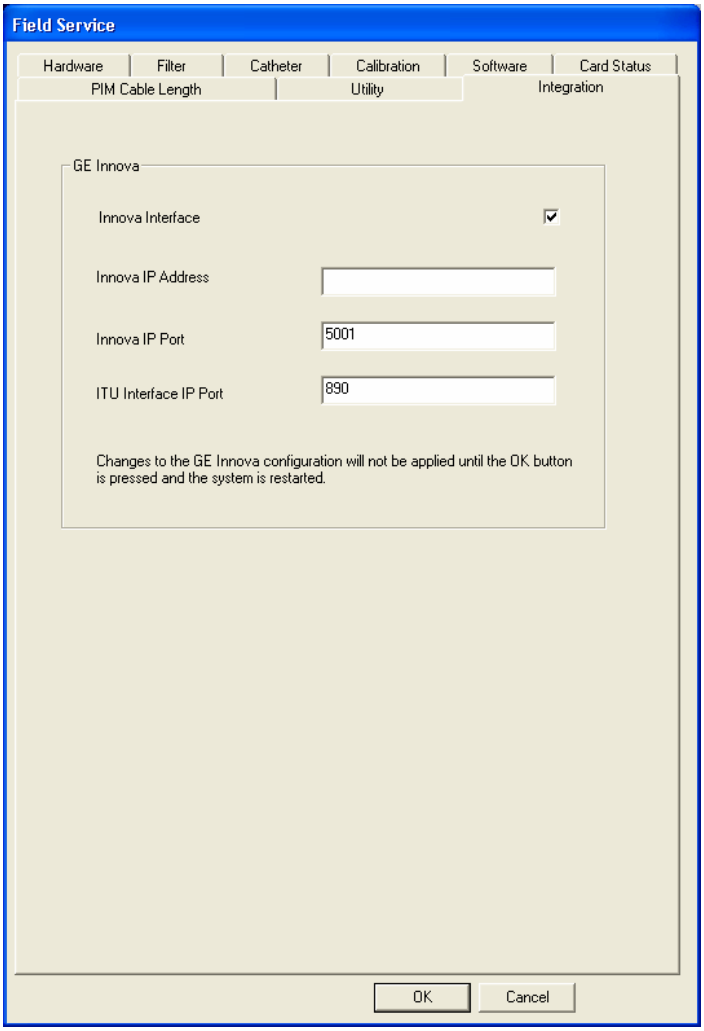


Figure 149 s5i Integration Page

The s5i integration page contains the information needed to configure the s5i to communicate with a properly configured Innova Angiography system. The Innova IP Address, Innova IP Port and ITU Interface IP Port should be entered into the s5i to configure the Innova IVUS interconnectivity feature set.

Appendix B General Technical Specifications

Catheter Specifications

Imaging Catheters

Transducer type: Piezoelectric

Frequency: 10 MHz for Visions PV 8.2F

20 MHz for Avanar, Eagle Eye *Gold*, Visions PV .018

360° view, multi-element solid state array transducer

Lumen characteristics: coaxial, guide wire lumen

Catheter	Shaft diameter	Transducer diameter	Maximum guide wire, in
Avanar F/X	2.9F (0.97 mm)	3.5F (1.17 mm)	0.014 (0.356 mm)
Eagle Eye *Gold*	2.9F (0.97 mm)	3.5F (1.17 mm)	0.014 (0.356 mm)
Visions PV .018	3.0F (1.00 mm)	3.5F (1.17 mm)	0.018 (0.457 mm)
Visions PV 8.2F	7.0F(2.33 mm)	8.2F (2.73 mm)	0.038 (0.965 mm)

Catheter	Minimum ID guiding catheter clearance	Length, cm	Diameters, mm
Avanar F/X	5F (1.67 mm)	150	8, 10, 12, 14, 16, 18, 20
Eagle Eye *Gold*	5F (1.67 mm)	150	8, 10, 12, 14, 16, 18, 20
Visions PV .018	6F (2.00 mm)	135	10, 12, 14, 16, 18, 20, 22, 24
Visions PV 8.2F	9F (3.00 mm)	90	20, 25, 30, 35, 40, 45, 50, 55, 60

NOTE: Additional information is available in the “Physicians Guide and Instructions for Use” that accompanies each catheter.

CPU Hardware

The s5i CPU is housed in a Supermicro CS733i Chassis with a Supermicro X6DAL-XG motherboard installed.

- Supermicro CS733i chassis
  - Mechanical
    - Medium Tower Workstation
    - Weight with all accessories less than 18,2 kg (40 lbs.)
    - Material: Steel, Aluminum, and Plastic Front Facing Panel
    - Finish: Black Powder coat on Metallic surfaces and Black Plastic.
    - Accommodate Supermicro X6DAL-XG-ATX motherboard
    - At least two 3.5" drive bays with 3.5" 250GB hard drives installed
    - One 5.25" externally accessible drive bay with DVD-R installed
  - EMI/RFI
    - Design overlapping seams with RFI suppressing contact fingers.
    - Chassis design supports IEC 60601-1-2 EMC requirements
  - Cooling
    - Front to back, flow thru employing three 120 mm low speed fans.
    - Will not overheat with only one fan working.
  - Power Supply
    - Ultra-quite operation,
    - IEC 60950 compliant,
    - 645W output,
    - 100-240 VAC, 50/60Hz, auto ranging
  - Input/Output
    - Four USB 2.0 interfaces
    - One 10/100/1000 BaseT interface
    - Keyboard and mouse PS2 interfaces
    - DVI video interface
    - VGA video interface
    - ECG input
    - Patient Interface Module (PIM) Interface
    - AC power input
    - Audio (line input and line output)

- Supermicro X6DAL-XG ATX dual Xeon motherboard
  - Two low voltage Xeon's processors installed
  - Two full length 5V 33MHz PCI interfaces with proprietary IVUS cards installed
  - One PCIe 16x Open GL compatible interface with Sapphire X1600 512MB video card installed
  - 2GB system RAM installed
  - One 10/100/1000 BaseT "GigE" network interface
  - Four USB 2.0 interfaces
  - Two SATA interfaces with two 250GB 7200rpm hard disk drives installed
  - One IDE interface with Pioneer DVR-110 drive installed
  - On board AC'97 Audio (Line In, Line Out)

Isolation Transformer Hardware

The isolation transformer is an off-the-shelf device made by Toroid corporation of Maryland. The transformer model number ISB-060M. There are no field serviceable components within the isolation transformer.

Isolation Transformer

- Mechanical
  - Size:
    - 8.9cm Height x 16.5 cm Width x 26.7 cm Depth
    - 3.5" Height x 6.5" Width x 10.5" Depth
  - Weight: 6.0 kg (13 lbs)
  - Material: sheet metal enclosure
  - Mounting:
    - Floor use with four non-skid pads
  - IEC 60601-1 compliant
- EMI/RFI
  - Complies with IEC 60601-1-2 requirements
- .Cooling
  - .Convection
- Power
  - AC power 600 VA
- Input/Output
  - IEC 60320 C13 input and
  - IEC 60320 C14 outlets (X6)
  - Devices on isolated power:
    1. The s5i CPU (Workstation)
    2. Control room monitor
    3. 4-way VGA video switch
    4. Olympus P11 Printer

Control Station Hardware

The Control Station is housed in a custom plastic enclosure and utilizes the same membrane control panel as the Volcano s5i tower (roll around cart) system. There are no field serviceable components within the Control Station.

Control Station

- Mechanical
  - Size:
    - 10cm Height x 33 cm Width x 17.75cm Depth
    - 4" Height x 13" Width x 7" Depth
  - Weight: 3.6 kg (8 lbs)
  - Material: UL 94 V-2 Compliant
  - Mounting:
    - Table top use with four non-skid pads
    - Custom bedside rail mounting kit with two hand screws
    - A 100mm VESA style, threaded hole pattern, centered on the base plate for other mounting applications
  - Control panel angle of incline is 15°.

  - The control station meets the fluid ingress requirements of IEC529 IPX0 when configured for NORMAL USE and when covered by a sterile drape.
- EMI/RFI
  - Complies with IEC 60601-1-2 requirements
- .Cooling
  - .Convection
- Power
  - USB powered device (+5 Volts DC @ 300mA)
- Input/Output
  - USB 1.1
  - Potential equalization ground post
  - The Control Station complies with USB standards in that it enumerates (automatically creates a unique number for itself) so that multiple devices can be connected simultaneously.

Joystick Hardware

The Joystick is housed in a stainless steel enclosure. The Joystick is an off-the-shelf device. There are no field serviceable components within the Joystick.

Joystick

- Mechanical
  - Size:
    - 2.5cm Height x 10cm Width x 7.5cm Depth (Stick height not included)
    - 1" Height x 4" Width x 3" Depth (Stick height not included)
  - Weight: 0.5 kg (1 lbs.)
  - Material: Stainless Steel
  - Mounting: Bedside rail mounted using single hand screw
  - The Joystick meets the fluid ingress requirements of IEC529 IPX0 when configured for NORMAL USE when covered by a sterile drape.
- EMI/RFI
  - Designed to comply with IEC 60601-1-2 requirements
- .Cooling
  - .Convection
- Power
  - USB powered device (+5 Volts DC @ 300mA)
- Input/Output
  - USB 1.1
  - Potential equalization ground post

Control Room Monitor Hardware

The control room monitor is an off-the-shelf NEC 1990Sxi 19" flat panel LCD monitor. There are no field serviceable components within the control room monitor.

Control Room

- Mechanical
  - Dimensions
    - 44.6 - 59.6 cm Height x 33.0 cm Width x 24.7 cm Depth
    - 16.9 - 21.0 inches Height x 13.0 inches Width x 9.7 inches Depth

  - Weight:
    - With stand: 9 kg (19.8 lbs.)
    - Without stand: 6.3 kg (13.8 lbs.)
  - Material: Plastic
  - Mounting:
    - Manufacturer supplied stand
    - Optional wall mounted swing arm kit
- EMI/RFI
  - Class B part 15 FCC compliant
- .Cooling
  - .Convection
- Power
  - Isolated AC power (100-240V 50/60Hz, 0.63-0.27A)
- Input/Output
  - DVI-D
  - DVI-I
  - VGA
  - AC input

4-way VGA Video Switch Hardware

The 4-way video VGA switch is an off-the-shelf Extron SW4 VGArs video switch. There are no field serviceable components within the video switch.

Control Room

- Mechanical
  - Dimensions
    - 4.4 cm Height x 22.2 cm Width x 24.1 cm Depth (Depth excludes connectors.)
    - 1.75" Height x 8.75" Width x 9.5" Depth (1U high, half rack wide)
  - Weight: 0.5 kg (2.2 lbs)
  - Mounting:
    - Desktop
    - 1RU rack mounting hardware available from manufacturer
- EMI/RFI
  - Class A part 15 FCC compliant
- .Cooling
  - .Convection
- Power
  - Isolated AC power (100-240V 50/60Hz, 10W)
- Input/Output
  - Four VGA inputs
  - One VGA output
  - One RS-232 remote control input
  - AC input

PIM Hardware

The PIM electronics are sealed in a plastic enclosure. There are no field serviceable components within the PIM.

- Mechanical
  - Dimensions
    - 4.1 cm Height x 9.9 cm Width x 21.2 cm Length
    - 1.6" Height x 3.9" Width x 8.4" Length
  - Weight: 0.7kg (1.5 lbs)
  - Mounting:
    - Magnet backing for storage
    - Beside mounted PIM holder
- EMI/RFI
  - IEC 60601-1-2 class A compliant
- .Cooling
  - .Convection
- Power
  - Custom DC-DC power supply from s5i
  - IEC 60601-1 type CF defibrillator proof applied part
- Input/Output
  - PIM to s5i interface
  - Volcano synthetic aperture catheter interface.

Printer Hardware

The Printer is an off-the-shelf Olympus P11 Printer. There are no field serviceable components within the Printer.

Control Room

- Mechanical
  - Dimensions
    - 18.4 cm Width x 18.0 cm Depth x 15.8cm Height (P11 only)
    - 7.2" Width x 7.1" Depth x 6.2" Height (P11 only)
  - Weight: 2.2 kg (5 lbs.)
  - Mounting:
    - Desktop
- EMI/RFI
  - Class B part 15 FCC compliant
- .Cooling
  - .Convection
- Power Supply
  - IEC 60601-1 compliant
  - Input 100-240 50/60Hz auto ranging
  - 24VDC 2.5A output
- Input/Output
  - USB 1.1 interface
  - 24VDC power input (P11 body)
  - AC power input (power supply)

Video

External Video Support

	Video Format	Frequency	Lines
USA	NTSC	60 Hz interlaced	525
Europe	PAL	50 Hz interlaced	625

Console Video Display Format

- DVI (s5i)- VGA(s5i)
- 1280 x 1024 pixel resolution
- 60 to 75 Hz refresh

Image

- Live/Still modes
- Variable frame rate
- 360° image
- Multiple depth scaling

Image Sizes

Image Mode	Image Area (in pixels)
Max IVUS	750 x 750

Video Inputs and Outputs

Composite video out

- 2 BNC video output connections (s5i only)
- VGA Output connector

SVGA output

- Standard computer monitor VGA output

Video Out (s5i)

- VGA/DVI

Dimensions and Weights-s5i

	Height, in	Width, in	Depth, in	Weight, lb
CPU	16.5	6.75	21.25	~35
Controller	5.0	15.0	10.0	~6.6
Monitor	17.5	18.0	10.0	~35
Patient Interface Module	1.6	4.0	7.4	~4.4

	Height, cm	Width, cm	Depth, cm	Weight, kg
CPU	39.6	16.2	51	~15
Controller	12	36	24	~3
Monitor	42	43.2	24	~15
Patient Interface Module	3.8	9.6	17.75	~2

Power – s5i (TUV Certified)

Systems Input:

100V~
120 V~
220-240V~
50/60Hz, 600VA

Computer Workstation Input:

100-240V~
50/60Hz, 250VA

Fusing

Use Agency approved fuses only, 250V. The transformer has an internal thermal resettable fuse.

- 100 VAC-8AT
- 120 VAC-6.3AT
- 220-240 VAC-3.15AT

Recording devices

- Hardcopy Digital Photo printer
- DVD writer in CPU
- Remote USB DVD Burner

Classifications

Per IEC 60601-1-2:2001, the Volcano s5 has these classifications:

Type of Protection against Electric Shock	Class I
Degree of Protection against Electric Shock	Type CF, defibrillation proof
Degree of Protection against the Harmful Ingress of Water	Ordinary
Degree of Safety of Application in the Presence of Anesthetics	Equipment NOT suitable for use in the presence of a flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide
Mode of Operation	Continuous Operation

EMC Statement

This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2001, Medical Device Directive 93/42/ EEC or the Electromagnetic Compatibility Directive 89/336/EEC (use applicable directive). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

Electrical Safety

Type CF Equipment: The heart symbol with the paddles on each side indicates that the patient interface module meets all requirements for International Electro technical Commission 60601-1 type CF classification. This device is protected against the voltages of defibrillation, however, it is recommended to disconnect the catheter from the patient interface module prior to defibrillation. If medically possible, remove the catheter from the patient prior to defibrillation.

System has to be installed to IEC 60601-1-1 (Medical Systems), including the use of an isolation transformer and potential equalization on control console and workstation.

Environmental Conditions

	Temperature, °F	Relative Humidity, % non-condensing	Altitude, ft
Operating	60-90	5-85	10,000
Storage*	60-122	5-85	—
Shipping*	60-140	5-85	35,000

*As per IEC 60601-1, section 10.1.

DICOM Image Storage

Saving patient cases to DVD: The archived images are stored in DICOM format with Volcano s5 system acting as a File Set Creator (FSC), following the guidelines in the 2004 DICOM 3.0 specification.

The DICOM images will be stored using the Ultrasound Application Profile STD-US-SC-MF-DVD, using the UIDs in the following table.

Information Object Definition	SOP CLASS UID	Transfer Syntax UID
DICOMDIR	1.2.840.10008.1.3.10	1.2.840.10008.1.2.1
Ultrasound Multi-frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1	1.2.840.10008.1.2.1 1.2.840.10008.1.2.4.50

Sending patient cases to a DICOM server: The Volcano s5 supports the ultrasound multi-frame image storage SOP Class as an SCU (Service Class User). The SOP Classes supported by the Volcano s5 system are categorized in the following table.

Information Object Definition	SOP CLASS UID	Transfer Syntax UID
Verification	1.2.840.10008.1.1	1.2.840.10008.1.2
Ultrasound Multi-frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1	1.2.840.10008.1.2 1.2.840.10008.1.2.1 1.2.840.10008.1.2.4.50

For more information, see the Volcano s5 DICOM Conformance Statement located on line at: http://www.volcanocorp.com/pages/products/s5/productinfo/s5_DCS.pdf

Accessories and Replacement Parts

Olympus P-11 printer paper and ink cartridge kit	804206-002
AC Power Cable, 120V	804409-001
AC Power Cable, 240V	01089
Volcano s5 Operator's Manual	804209-001

Catheters

Visions PV 8.2F (over-the-wire)	K8888900
Visions PV .018	K8886700
Avanar F/X	K8885700
Eagle Eye™ *Gold* F/X	701408-001

Standards and Regulations

The s5 Family of Intravascular Ultrasound Imaging Systems complies with the requirements of these standards and requirements:

Medical electrical equipment – General requirements for safety

EN 60601-1:1990 + A1:1993 + A2:1995

IEC 60601-1:1988 + A1:1991 + A2:1995

Medical electrical equipment – Electromagnetic compatibility

EN 60601-1-2:2002/IEC 60601-1-2:2001

SYMBOL: Declaration of Conformity:

We declare that the s5 Family of Imaging Systems meets the requirements of the EC-Directive 89/336/EEC Electromagnetic Compatibility (EMC) and complies with the following standards:

Guidance and Manufacturer's declaration – electromagnetic emissions S5 Family		
The S5 Family is intended for use in the electromagnetic environment specified below. The customer or the user of the S5 Family should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment-guidance
IEC/EN 60601-1-2:2001	Group 1, Class A	All ISM equipment in which there is intentionally generated and/or used conductively coupled radio frequency energy which is necessary for the internal functioning of the equipment itself. Equipment suitable for use in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies building used for domestic purposes.
EN 61000-3-2		
EN 61000-3-3		

Guidance and Manufacturer's declaration – electromagnetic immunity S5 Family			
The S5 Family is intended for use in the electromagnetic environment specified below. The customer or the user of the S5 Family should assure that it is used in such an environment.			
Immunity Test	Test Level	Compliance Level	Electromagnetic environment-guidance
EN 61000-4-2:1995 Including A1:1198 and A2:2001 IEC 61000-4-2:1995 Including A1:1998 and A2:2000 (Electrostatic Discharge)	Contact ± 6kV Air ± 8kV	Contact ± 6kV Air ± 8kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
EN 61000-4-3:2002 Including A1:2002 IEC 61000-4-3:2002 Including A1:2002 (Radiated)	Field Strength 3 V/m Frequency Range 80MHz - 1GHz, 1GHz - 2.5GHz AM: 80% 1KHz sine wave 1% step, all four sides radiated	Field Strength 3 V/m Frequency Range 80MHz - 1GHz, 1GHz - 2.5GHz AM: 80% 1KHz sine wave 1% step, all four sides radiated	Portable and mobile RF communications equipment should be used no closer to any part of the s5i, including cables than the recommended separation distance calculated below: $d \cong 2\sqrt{ERP}$ where d = distance in meters and ERP = Effective Radiated Power in Watts. Field Strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range.
EN 61000-4-4:1995 Including A1:2000, 2001 IEC 61000-4-4:1995 Including A1:2000,	Pulse Amplitude & Polarity (Power Lines) ± 2 kV Data Lines and DC lines ± 1kV	Pulse Amplitude & Polarity (Power Lines) ± 2 kV Data Lines and DC lines ± 1kV	AC power quality should be that of a typical hospital environment.

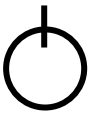
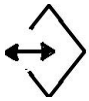
A2:2001 (Electrical Fast Transient/Burst)	 Repetition Rate: 5kHz Duration ≥ 1 minute	 Repetition Rate: 5kHz Duration ≥ 1 minute	
EN 61000-4-5:1995 Including A1:2001 IEC 61000-4-5:1995 Including A1:2000 (Surge)	Surge Amplitude Common Mode 0.5, 1.0, 2.0kV Differential Mode 0.5 & 1.0kV 5 surges per angle Angle 90º, 180º, 270º Polarity ± Repetition 1 surge per minute	Surge Amplitude Common Mode 0.5, 1.0, 2.0kV Differential Mode 0.5 & 1.0kV 5 surges per angle Angle 90º, 180º, 270º Polarity ± Repetition 1 surge per minute	AC power quality should be that of a typical hospital environment.
EN 61000-4-6:1996 Including A1:2001 IEC 61000-4-6:1996 Including A1:2000 (Conducted)	Amplitude 3 Vrms Frequency Range 150kHz to 15MHz Amplitude 3 Vrms Frequency Range 15MHz to 50MHz Amplitude 3 Vrms Frequency Range 50MHz to 80MHz Modulation 80%, 1kHz sine wave 1% step	Amplitude 3 Vrms Frequency Range 150kHz to 15MHz Amplitude 0.3 Vrms Frequency Range 15MHz to 50MHz Amplitude 3 Vrms Frequency Range 50MHz to 80MHz Modulation 80%, 1kHz sine wave 1% step	AC power quality should be that of a typical hospital environment
EN 61000-4-8:1993 Including A1:2001 IEC 61000-4-8:1993 Including A1:2000 (Power Frequency	3 A/m 50Hz, 60Hz	3 A/m 50Hz, 60Hz	If image distortion occurs, it may be necessary to position the s5i further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field

Magnetic Field)			should be measured in the intended installation location to assure that it is sufficiently low.
EN 61000-4-11 Including A1:2001 IEC 61000-4-11:1994 Including A1:2002 (Voltage Dips and Interrupts)	@ 240V, 50Hz 100% dip 10 msec 5000 msec 60% dip 100 msec 30 % dip 500 msec @120V, 60Hz 100% dip 8.33 msec 5000 msec 60% dip 83.33 msec 30 % dip 416.6 msec @100V, 60Hz 100% dip 8.33 msec 5000 msec 60% dip 83.33 msec 30% dip 416.6 msec	@ 240V, 50Hz 100% dip 10 msec 5000 msec 60% dip 100 msec 30 % dip 500 msec @120V, 60Hz 100% dip 8.33 msec 5000 msec 60% dip 83.33 msec 30 % dip 416.6 msec @100V, 60Hz 100% dip 8.33 msec 5000 msec 60% dip 83.33 msec 30% dip 416.6 msec	AC power quality should be that of a typical hospital environment. If the user of the S5I requires continued operation during AC power interruptions, it is recommended that the S5I be powered from an uninterruptible power supply.

Caution: The InVision Gold 3 should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used

CE 0086 COMPLIES WITH THE COUNCIL DIRECTIVE 93/42/EEC

Symbols

CE 0086	Complies with the Council Directive 93/42/EEC
	Power Off
	Power On
	Attention, Consult Accompanying Documents
	Power On/Off
	Patient Interface Module (PIM) Connector
	Output Signal
	Equipotentiality
	This device is protected against the voltages of defibrillation
	Input for the catheter connector
	Indicates a strong magnetic field is present

Appendix C- DICOM

DICOM Settings

DICOM stands for Digital Imaging and Communications in Medicine. It is an image format for medical images that has been standardized so that images from different types of medical electronic equipment can be shared on a common computer network. The intravascular ultrasound images from your Volcano s5 can be sent to a network within a hospital or clinic, or to a network of health care providers. Sending images to a remote computer using a standardized format may be able to provide physicians with quicker access to medical information for more rapid diagnoses and treatment decisions.

The DICOM Settings dialog box should be set up by either a Volcano Corporation field service representative or the Information Systems manager or network administrator at your facility. The following information briefly describes the selections that can be made.

Configuring the DICOM/Network

To configure settings for DICOM and Networking:

1. Press the **Settings** key on the control panel. The Settings dialog box displays.
2. In the Archive tab area of the Settings dialog box, click the DICOM **Configuration Dialog** button. The DICOM Network Configuration dialog box displays, as shown below.

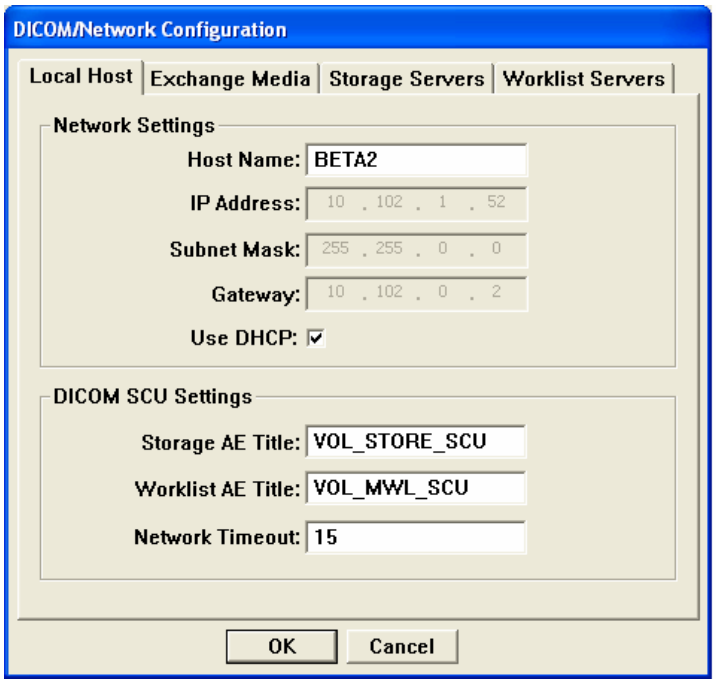


Figure 150: DICOM Settings-Local Host Dialog Box

NOTE: After changing the Local Host settings you need to power down the system for the new settings to take effect. The system powers down, starts up, then powers down and restarts again.

Local Host–Network Settings

- **Host Name:** The factory hostname default is "s5." If necessary, enter the computer host name for the Volcano s5 system.
- **IP Address:** Enter the network Internet Protocol (IP) address for the system.
- **Subnet Mask:** The Volcano s5 systems use the Subnet mask to determine if communication with the remote host needs to be routed through a gateway. If so, enter the the Subnet mask for the system's sub network.
- **Gateway:** Enter the gateway IP address for the system.
- **Use DHCP:** Check this box if DHCP (Dynamic Host Configuration Protocol) is used to configure the system's IP address.

Local Host–DICOM SCU Settings

- **Storage AE Title:** The Application Entity Title field is used to configure the AE title for the local DICOM Store SCU (Service Class User) application running on the Volcano s5 system. The factory default is **VOL_STORE_SCU**. If necessary, enter another value.
- **Worklist AE Title:** Enter the AE title for the Worklist.
- **Network Timeout:** Used to configure the DICOM Association Response Timer and other network timeouts. This timer is used to terminate the DICOM association (network connection) if communication between systems stops. The factory default is 15. If necessary, enter another value.

Exchange Media

- Select the compression desired for DICOM DVD Exchange Media. The following selections are available:
  - No compression
  - JPEG High Quality
  - JPEG Medium Quality
  - JPEG High Compression

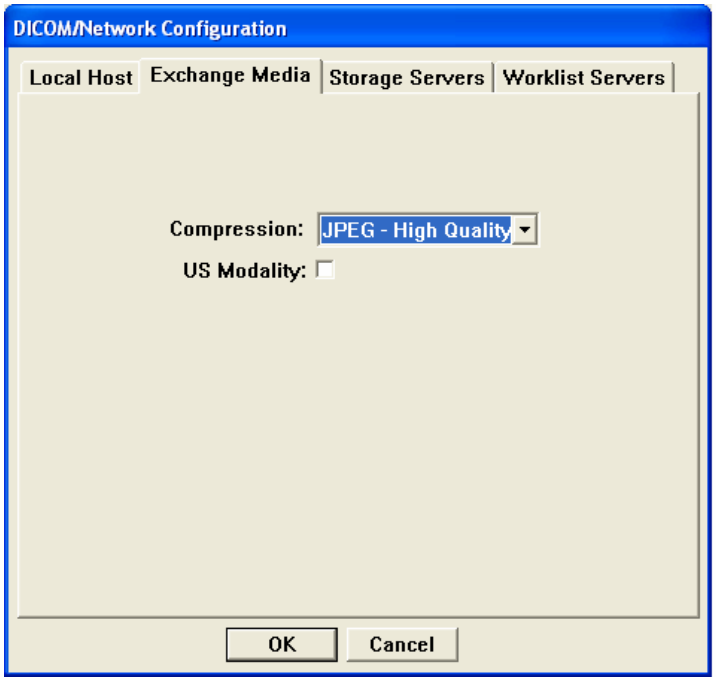


Figure 151: DICOM Settings-Exchange Media Dialog Box

- **US Modality**: Select a write mode. When checked, images will be written to DVD using the US Modality. When unchecked, images are stored using the IVUS Modality.

Storage Servers

- **Select Server:** Select a DICOM Store Server. Multiple Servers may be configured on the Volcano s5 system. This drop down contains the list of configured servers. The currently selected server will be used for subsequent configuration changes and will also be the server that receives DICOM images from the s5 system during an Archive to Network operation.
- **New Server**: To specify a new DIACOM server, enter the name here. This is a user-friendly alias used to identify a remote DICOM Storage Server. Once the name is typed, pressing either the Enter key or selecting the Add button causes the new Server to be created and added to the DICOM Server List. The newly added server becomes the currently selected Server. For example:
  - Cardiology Lab Server
  - Cardiology Lab Backup
  - Radiology PACS
- **Add**: Pressing this button adds a new server to the DICOM Storage Server list. This button is disabled if nothing has been entered in the New Server field.
- **Delete**: Pressing this button deletes the currently selected server from the DICOM server list. The next server in the list becomes the currently selected server.

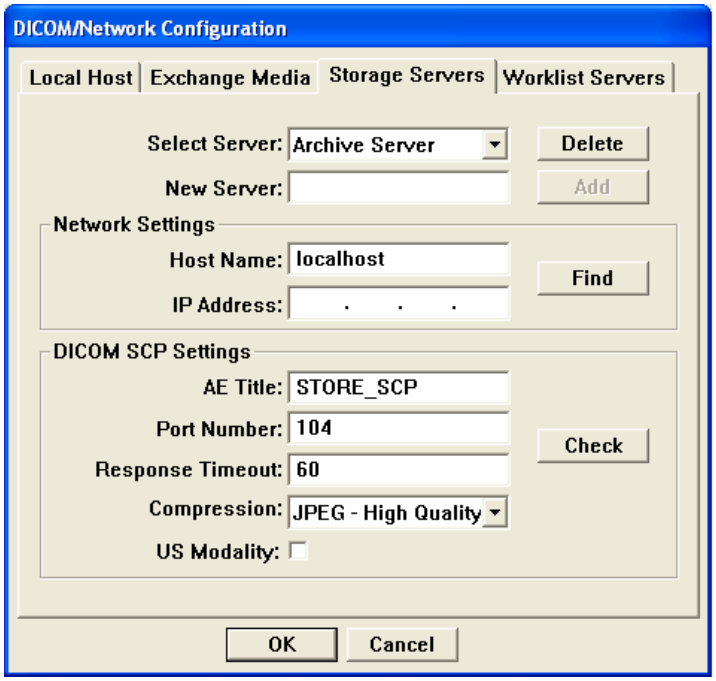


Figure 152: DICOM Settings-Storage Servers Dialog Box

Storage Servers–Network Settings

- **Host Name:** This field contains the remote computer's host name that the Volcano s5 system will be sending DICOM images. If you are adding a new server, enter the host name of the server here.
- **IP Address:** This field contains the Internet Protocol (IP) address that the Volcano s5 system will be sending DICOM images. If you are adding a new server, enter the IP address of the server here.
- **Find:** The Find button performs a Network PING operation to find the configured remote computer. If a remote computer host name is entered and no IP Address is used, the IP Address of the successfully resolved host name is automatically populated in the IP Address field. If both the host name and IP Address are entered, then the IP Address is used for the PING instead of Host Name resolution.

Storage Servers–DICOM SCP Settings

- **AE Title**: This field is used to configure the Application Entity Title field of the remote DICOM Store SCP (Service Class Provider) application to which the Volcano s5 system will be sending images. The factory default is **STORE_SCP**. If necessary, enter another value.
- **Port Number**: This field is used to configure the port number to which the remote DICOM Store SCP application will be listening for messages from the Volcano s5 system. The factory default is 104. If necessary, enter another number.
- **Response Timeout:** This field is used to configure the amount of time (in seconds) that the system will wait for a response from the remote DICOM Store SCP (Service Class Provider) server after an image has been sent. This timer is

used to terminate the DICOM association (network connection) if communication between systems stops. The range for this value is 10 to 600 seconds. The factory default is 60. If necessary, enter another value.

- **Compression:** Select a compression for sending images to the remote DICOM Storage server. The following selections are available:
  - No compression
  - JPEG High Quality
  - JPEG Medium Quality
  - JPEG High Compression
- **Check Button:** This button is used to test the connection between the Volcano s5 DICOM SCU and the remote DICOM Storage SCP. The connection is tested using the DICOM C-ECHO service (Verification class).
- **US Modality:** When checked, images will be transferred to remote storage servers using the US Modality. When unchecked, images are transferred using the IVUS Modality.

Worklist Servers Configuration

This section describes the DICOM Configuration Dialog - Worklist Servers Configuration. The following parameters are configurable for the each defined Remote DICOM Modality Worklist SCP Server.

- **Select Server**: Select a server from the from the Server List for configuration
- **New Server**: To specify a new server, enter the name in this field.
- **Add**: Adds the New Server to the Server List.
- **Delete**: Removes the currently selected server from the Server List.

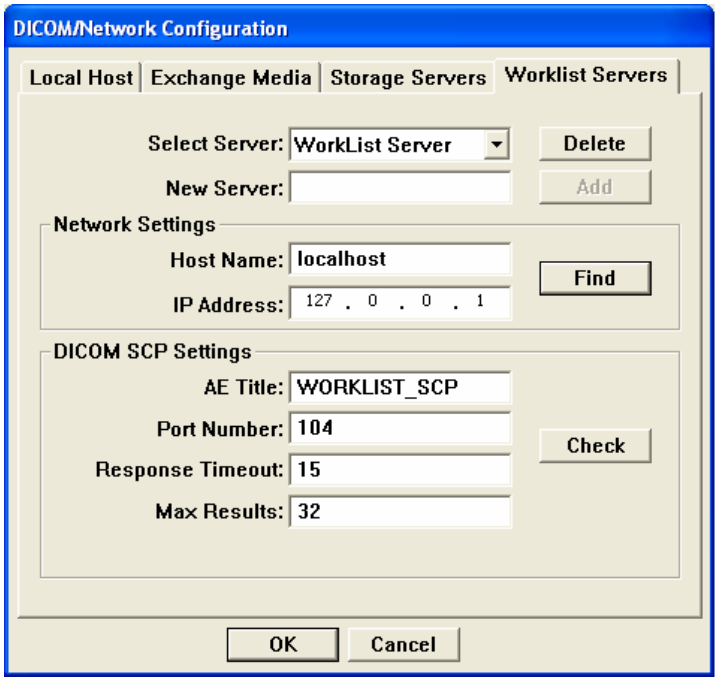


Figure 153: DICOM Settings-Worklist Servers Dialog Box

Worklist Server - Network Settings

The following network parameters are configurable for the each defined Remote DICOM Storage SCP Server

- **Hostname**: Computer Hostname of the remote device. If you are adding a new server, enter the host name of the server here.
- **IP Address**: IP Address of the remote device. If you are adding a new server, enter the IP address of the server here.
- **Find**: Performs a network PING to determine in the configured device is connected to the network. Find will perform IP address resolution if only the remote hostname is entered.

Worklist Server - DICOM SCP Settings

The following DICOM parameters are configurable for the each defined Remote DICOM Storage SCP Server.

- **AE Title**: Application Entity Title. This parameter is used to identify the remote DICOM Modality Worklist SCP application. If necessary, enter another value.
- **Port Number**: Identifies the port that the remote DICOM Modality Worklist SCP application is listening on. If necessary, enter another value.
- **Response Timeout**: DICOM C-FIND Response Timeout for the remote Modality Worklist SCP. If necessary, enter another value.
- **Max Results**: Limits the maximum number of Scheduled Procedure results that the system will accept from the Modality Worklist SCP server. When this limit is exceeded, a C-FIND cancel request is sent to the Worklist Server and no more results are accepted. The Max Results value is used for all defined Worklist SCP Servers. If necessary, enter another value here.
- **Check**: Performs a DICOM C-ECHO (Verification service) with the configured Modality Worklist SCP to determine if the remote application is on-line.

S5 DICOM Conformance Statement

The s5 DICOM Conformance Statement can be found in Appendix J.

The s5 and s5i systems share the same DICOM conformance statement. To download the latest s5 DICOM Conformance Statement Please follow the below URL:

http://www.volcanocorp.com/files/pdf/s5_DCS.pdf

Appendix D Glossary

Acoustic reference: The collection of an acoustic reference removes the universal minor image imperfections called ring down artifact, which is caused by catheter noise and offset characteristics.

Diameter: The depth of field to which the ultrasound image data is acquired.

DICOM (Digital Imaging and Communications in Medicine): A format for storing images on DVD and transferring images and patient data over a network. The DICOM standard facilitates the exchange of patient images and data among different pieces and types of medical imaging equipment.

Gain: The intensity of the ultrasound echoes; a higher gain setting results in a brighter image with more intense echoes.

In-Line Digital: Two-dimensional, 360° rotation, real-time longitudinal view generated by visually “stacking” hundreds of cross-sectional intravascular ultra-sound images.

GE ITU-(Innova Touch Screen)-The GE ITU is a touch screen device that can connect to and control the Volcano s5i system. The following s5i functions are mapped to the GE ITU:

- Home/(live),
- Play,
- Stop,
- Record,
- Save Frame,
- Bookmark,
- Ring Down,
- VH IVUS,
- ChromaFlo,
- Measure,
- Print
- Measure, ChromaFlo, VH

Patient Interface Module (PIM): The imaging catheter connects to the Patient Interface Module which excites the catheter’s transducer elements to transmit ultrasonic energy to the surrounding tissue. The PIM amplifies and processes the resultant echo signals from the transducer.

Post-processing: Any operation conducted on a stored ultrasound image; measurements, annotations, and retrieving and clearing data are examples of post-processing.

Ring down Artifact: Ring down artifact is a result of multiple phenomena: 1) acoustic and RF signal crosstalk between neighboring acoustic elements on synthetic aperture catheters, and 2) the innate physical properties of ultrasound crystals. The physical properties of the materials used in the catheter tips, along with the operating frequency, temperature, and the size and geometry of the ultrasound elements contribute to the magnitude and appearance of the artifact.

Sensitivity: During ChromaFlo imaging, blood/ luminal flow rates can vary from 4 cm/sec up to 110 cm/sec. The Volcano s5 is equipped to display in color 5 viewable flow ranges. This capability is accessed via the Sensitivity control available on the Adjust Image menu. There are 5 selections: Sensitivity 1 for high flow rate vessels and Sensitivity 5 for low flow rate vessels. Typically Sensitivity 3 through 5 will provide the best visualization of coronary vessel flow rates.

For any given Sensitivity setting, areas where the relative blood/ luminal flow rates are higher are more yellow; areas where they are slower are redder. By altering the Sensitivity setting, one can shift towards yellow the color of slower moving areas of blood flow; by decreasing the Sensitivity setting to a lower value, one can shift towards red the color of faster moving areas of blood flow.

Appendix E– Field Service Bulletins

Appendix F Capture System Settings

Click his link to open a PDF form that should be used to capture the system settings prior to performing a software installation.

Appendix G Mother Board User's Guide

Motherboard Audible and Visual Alarms

BIOS Error Beep/Post Codes

During the POST (Power-On Self-Test) routines, which are performed each time the system is powered on, errors may occur.

Non-fatal errors are those which, in most cases, allow the system to continue the boot-up process. The error messages normally appear on the screen.

Fatal errors are those which will not allow the system to continue the boot-up procedure. If a fatal error occurs, you should consult with your system manufacturer for possible repairs.

These fatal errors are usually communicated through a series of audible beeps. The beep codes are listed below. All errors listed, with the exception of Beep Code 8, are fatal errors.

POST codes may be read on the debug LEDs located beside the IDE connector on the motherboard backplane. See the description of the Debug LEDs (DS7 and DS8) below.

AMIBIOS Error Beep Codes

Beep Code	Error Message	Description
1 beep	Refresh	Circuits have been reset. (Ready to power up.)
5 short, 1 long	Memory error	No memory detected in system
8 beeps	Display memory read/write error	Video adapter missing or with faulty memory

Onboard Indicators

G-bit LAN Right LED Indicator

LED Color	Definition
OFF	No Connection
GREEN	100 MHz
ORANGE	1 GHz

SATA LED Pin Definitions (JSLED)

Pin #	Definition
1-5	No Connection
6	Intel 6300ESB SATA Activity LED
7	Intel 6300ESB SATA Activity LED
8-9	No Connection

On board LED Pin Definitions

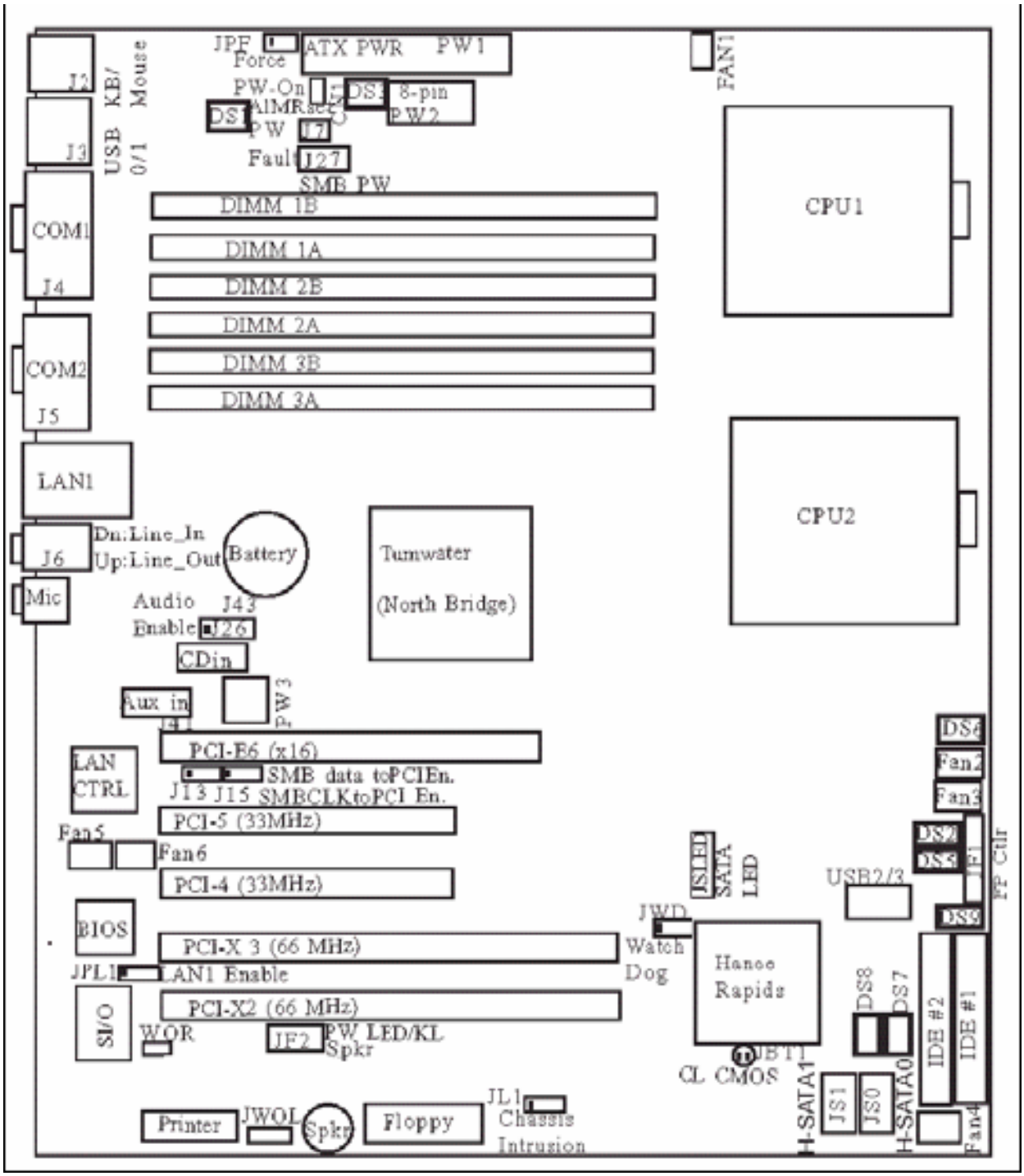
LED(s)	Definition
DS1	CPU PWR good or CPU +12V PWR
DS2	CPU2 VRM Overheat
DS3	CPU1 VRM Overheat
DS5	PWR LED
DS6	CPU Overheat

DS7/DS8 LED Post Codes

DS7	DS8	Description/Message
ON	ON	PWR On
ON	OFF	SPD Read OK
OFF	ON	Memory Size-OK
OFF	OFF	Starting Bus Initialization

System Alert LED

DS9	Definition
GREEN	System: On and OK
YELLOW	System: Off, PWR Cable Connected
RED	PWR or CPU failure



SuperMicro X6DAL-XG Mother Board

Click this link to open the complete manufacturer's motherboard users guide.

Appendix H Monitor User's Guide

Click this link to open the monitor manufacturer user's guide.

Appendix I Printer User's Guide

Click this link to open the printer manufacturer user's guide.

Appendix J s5 DICOM Conformance Statement

The s5 and s5i systems share the same DICOM conformance statement. To download the latest s5 DICOM Conformance Statement Please follow the below URL:

http://www.volcanocorp.com/files/pdf/s5_DCS.pdf

Click this link to open a PDF copy of the latest s5 DICOM conformance statement as of the release of this service manual.

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